Guidance for FDA Staff

Compliance Program Guidance Manual: Field Compliance Testing of Diagnostic (Medical) X-ray Equipment

Document issued on: March 15, 2000

This document supersedes the Compliance Program Guidance of Diagnostic (Medical) X-ray Equipment document issued in 1998.

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Diagnostic Devices Branch
Division of Enforcement I
Office of Compliance

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, Henry Knox, HFZ-322, 2094 Gaither Rd., Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Henry Knox at (301) 594-4591, extension 161.

Additional Copies

World Wide Web/CDRH/ home page: http://www.fda.gov/cdrh/comp/guidance/1133.pdf
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SUBJECT:	IMPLEMENTATION DATE
Field Compliance Testing of Diagnostic (Medical) X-ray Equipment	Upon Receipt
	COMPLETION DATE: September 30, 2003

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
94DS	86003

FIELD REPORTING REQUIREMENTS

A. GENERAL

Routine Compliance Tests - Subsequent to accomplishing district auditor review, the auditor will distribute Field Test Record forms as follows:

- Original (White Copy) . . . . . Information Processing and Office Automation HFZ-307
- 1st (White Copy) . . . . . Home district auditor for review and filing
- Blue Copy . . . . . Regional Radological Health Representative (RRHR) for State file

* The following field test records shall be handled in the above manner with order of priority as listed below:

FDA 3071	General Information
FDA 2784	Abovetable X-ray Source Radiographic Systems
FDA 2786	Undertable X-ray Source Fluoroscopic and Spot Film Systems
FDA 3068	Peak Kilovoltage Determination
FDA 3260	C-Arm Fluoroscopic and Spot Film Systems
FDA 3069	Abovetable X-ray Source Fluoroscopic and Spot Film Systems
FDA 3261	Vertically Mounted Cassette Holder Radiographic Systems

FDA 2783 Mobile Radiographic Systems

FDA 3297 Head and Neck Radiographic Systems
FDA 2785 Dental Radiographic Systems
FDA 3070 Mammographic Systems
FDA 2782 Field Test Record Continuation Sheet

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- Beginning October 1, 1994, routine compliance testing of mammographic equipment will not be conducted by this compliance program unless approved under special consideration by the RRHR. The RRHR will contact the Center for Devices and Radiological Health (CDRH) to receive authorization for such tests. In addition testing of dental units will not be conducted routinely. The RRHR must be contacted to approve special testing for dental units.

- The Home District will verify corrections, review the CDRH status report of the Field Correction Action Report (FCAR) and ensure updates have been added to the CDRH computer. The Home District will also review incorrect or incomplete Reports of Assembly FDA 2579, obtain any necessary corrections from the assembler, and notify HFZ-307 of corrections.

  Submit all violative assembler inspection reports to the District Compliance Branch for review, evaluation, and classification prior to referral to CDRH, Division of Program Operations, HFZ-305. Do not send non-actionable inspection reports to HFZ-305.

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B. FACTS REPORTING

- The rules for what activities should be reported under each of the operation codes has not changed with the implementation of FACTS V.2. Therefore, the following guidelines should continue to be used:
- Report all time spent in reviewing and correcting FDA 2579s (Reports of Assembly) under Operation Code 13 (Investigations) in the FACTS "Maintain Investigations" screen. Time spent in correspondence (verbal/written) regarding FDA-2579s should be reported under this operation code also.

  Report all time spent in preparation, arranging the test, and on-site conducting of field tests under Operation Code 53 (Field Examination/Test) in the FACTS "Maintain Field Examination/Tests" screen since the test is an inspection of the assembler's performance. Enter the number of tests performed for the assembler on that date and also reference the field test record (FTR) number(s) in the description field.

  SPECIAL AUDITOR INSTRUCTIONS: When performing an on-site audit of an x-ray surveyor, a special entry must be made in FACTS. Time shall be reported as a field test (Operation Code 53) and includes preparation time, on-site time, test evaluation time, and audit result reporting time. In the Description Field, enter the words "Joint Test" followed by the code for the State or FDA District of the individual being audited. Enter also the GI test ID for the test which was conducted.

  Example: Joint Test NJ GI12344
  Joint Test DET GI12345

  Also, report as Operation Code 92, (Coordination/Technical Review) in the FACTS "Miscellaneous

Operations Accomplishment Hours" screen time spent as an Auditor for Field Test Record (FTR) review, Notification Letter or Warning Letter correspondence, FCAR submissions and updating of CDRH database, FTR computer updating, and response to FTR questions of compliance. The description field should list "Diagnostic X-ray Coordination". Time should be reported on a routine basis (weekly or quarterly depending on the volume) and may be combined for that time period.

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C. SPECIAL

Special procedures for reporting field tests are necessary when an x-ray system or component does not comply with the Federal standard. These procedures are detailed under the Operation Instructions of Part III A.1.d.7 & 8.

Special Compliance Tests - A data format for reporting special tests to the Diagnostic Devices Branch (HFZ-322) will be provided by CDRH on assignment.

Report newly identified assembler firms to CDRH, HFZ-307 by returning copies of assembler forms or submitting inspection reports and indicating in large red letters, in the upper left corner, the words "NEW ASSEMBLER" with their central file number.

Send copies of all correspondence generated under this program to HFZ-322. This includes copies of Warning Letters and the assembler's response when the response is a disputed noncompliance or where the assembler claims the original equipment manufacturer is responsible for the noncompliance. Include all evidence to support the allegation of manufacturer responsibility.

PART I - BACKGROUND

The Diagnostic X-ray Performance Standard (Reference 1) was promulgated in August 1974 to protect the public from unnecessary radiation hazards of diagnostic x-ray equipment. Since 1974, FDA and State personnel have conducted over 65,000 field tests of certified diagnostic x-ray systems for compliance with the standard.

The most prevalent items of major noncompliance identified under this program have been:

- Inoperable radiographic positive beam limitation (PBL) collimation systems.
- Excessive mis-sizing of the x-ray beam by the PBL system.
- Excessive fluoroscopic entrance exposure rate.
- Excessive misalignment of the fluoroscopic x-ray field with the image intensifier.
- Excessive misalignment of the x-ray field with the spot film image receptor.
- Failure of the primary protective barrier interlock for fluoroscopic systems.
- Insufficient illuminance of the light localizer for radiographic collimators.

These noncompliances also represent some of the most significant radiation hazards.

The highest rates of noncompliant systems (i.e., systems with one or more major noncompliances) have been for the more complex radiographic and fluoroscopic x-ray systems that require considerable calibration and adjustment by the assembler. Mobile and dental x-ray systems that require comparatively little adjustment by the assembler have had much lower rates of noncompliance.

Where field testing has identified generic or design related noncompliances, CDRH has required component manufacturers to initiate recalls to correct violative products. Since 1974, more than 60 such recalls have been initiated based in whole, or in part on field activities under this compliance program. The majority of the noncompliances identified through this program have been caused by incomplete or improper installations by x-ray assemblers. The initial reduction in noncompliance has come primarily from voluntary efforts by the x-ray industry to better train and equip assemblers and to require final system compliance testing. A stronger regulatory approach is necessary to prevent continued violative installations and to further reduce the noncompliance rate.

Notification letters are issued to assemblers each time a noncompliance is discovered by routine compliance field testing. The notification letter advises the assembler about each noncompliance and requests corrections on a case-by-case basis without requiring any formal recall or corrective action plan. When the assembler continues a pattern of violative assemblies, or refuses to correct cited violations, regulatory action (civil penalties and/or injunction) can be initiated. The documentation and inspections necessary for civil penalty/injunction

action can be time consuming and resource intensive on FDA and, therefore, an optional strategy has been devised which may be used separately or in conjunction with civil penalties and/or injunction. This additional strategy is a warning letter of declaration of assembler noncompliance with district ordered assembler recall (NC/DOAR). By this process, the assembler's installation program is considered noncompliant by FDA. Since an assembler is considered a manufacturer under Subchapter J Part 1000.3(n), all regulations pertaining to noncompliance declarations pertain to assemblers. This process will require the assembler to submit a formal corrective action plan (CAP) and initiate a recall. Should the assembler fail to comply with the NC/DOAR provisions, additional civil penalties can be charged for failure to notify and correct, (Section 538(a)(2).

Previously civil penalties could only be charged for systems for which FDA had field test data or documentation. The noncompliance declaration process includes all assemblies during the specified time applicable to the data analysis and will require the assembler to provide a CAP for all of them. Thus for failure to respond or inadequate response to the NC/DOAR, the assembler faces a greater number of violative charges than initially using the direct civil penalty approach.

Since this strategy is based on a sample of systems installed by the assembler, civil penalties will still be the choice of enforcement strategy for companies installing small numbers of systems.

PART II - IMPLEMENTATION

A. Objectives

This is a continuing, non-statistical compliance program intended:

1. To identify certified diagnostic x-ray systems that fail to comply with applicable performance standard requirements.

2. To obtain correction of noncompliant systems identified in (1) above.

3. To identify assemblers and manufacturers responsible for violative x-ray installations and take appropriate administrative/enforcement actions necessary to prevent further installations of noncompliant products.

This program is based primarily on monitoring of assembler certification reports (FDA 2579's) to identify installation sites, and on field testing (by FDA and State personnel) of x-ray systems at the user site. Inspections of assembler firms are intended primarily as follow-up to violations identified from field testing and FDA 2579 reviews, and to document reporting violations and to support legal action recommendations.

B. Program Management Instruction

1. Resource Instructions

District office interface with the automated data systems maintained by CDRH and the role of the x-ray auditor are critical factors for effective implementation of this program. All District Offices have direct entry capability of field test data into the CDRH data base and are responsible for timely data entry. Contact CDRH with any direct data entry problems. (See Attachment B).

The accomplishing district auditor is responsible for maintaining the competence of personnel to perform work under this program. These and other x-ray auditor functions are described in Part III.A.2. Only personnel qualified under Field Management Directive No. 125 may perform the auditor functions (see Attachment O). Districts without a qualified auditor must arrange with the regional office for an auditor from another district to perform their audit functions until a local district auditor can be qualified. OJT may be used to assist in training for the auditor position.

All field tests of diagnostic x-ray equipment shall be performed in accordance with test procedures provided by the CDRH in FDA publication number 81-8161 (Reference 4) with latest updates. Only field investigators with specialized training may perform x-ray field tests. Such training may consist of a formal course in x-ray survey techniques or in-house training arranged by the RRHR, but must include approximately two weeks of OJT with a qualified auditor.

All FDA personnel performing or participating in field tests shall wear personnel dosimeters issued by the Field Health Physicist at WEAC. State personnel will utilize the personnel dosimeter normally provided by their State program.

CDRH requires direct field test data entry using XRAYAPSY and strongly supports on-line interactive computer access for all Districts. CDRH provides routine and/or special reports (on request) in support of this compliance program. Information concerning potential test locations, assembler noncompliance trends, and assembler reporting are accessible and should be requested through the x-ray auditor and the district DPU.

2. Planning Instructions

Each District shall develop a strategy:

a. to concentrate proportionately more field testing and special monitoring for those assemblers with the highest volume of noncompliant installations and the highest rates of noncompliance (i.e., greatest negative public health impact) and those assemblers suspected of non-reporting installations and,

b. where necessary, to develop legal action cases in accordance with CPG 7133.12, to bring these violative assemblers into compliance.

For assemblers that make installations outside their home district, the FDA home district and accomplishing district must establish a strong liaison to monitor the assembler and develop evidence.

For Districts with state contract or partnership testing, the District office will work through the RRHR to have state testing concentrate on problem assemblers when appropriate. (Refer to Part II, B.5. - RRHR Management Activities).

Field test priorities are:

(1) Problem assemblers with the highest noncompliance rate as identified by routine reports from CDRH.

(2) Other problem assemblers known to the district.

(3) High volume assemblers of radiographic and fluoroscopic systems for whom very few systems have been tested.

(4) New assemblers of radiographic and fluoroscopic systems.

(5) Routine testing of randomly selected radiographic and fluoroscopic systems.

(6) Infrequent testing of dental and mobile x-ray systems, for training purposes or at the request of CDRH. Mammographic equipment will not be tested under this program except under authorization from CDRH. The MQSA testing program will cover mammographic equipment.

3. Legal Action Case Development

The primary enforcement mechanism against x-ray assemblers is Civil Penalties with an alternative enforcement mechanism of noncompliance declaration with district or region ordered assembler recall (NC/DOAR). Compliance Policy Guides 7133.12 (with revised alternative enforcement) and 7133.23 and Regulatory Procedures Manual (RPM) Chapter 6 provide guidance for developing case recommendations. Although the RPM points out that a health hazard is implicit in all performance standard violations, at this time actions will be approved only for those field tests which demonstrate more than a minimal health hazard (see Attachment D). Should violations continue, following the assembler's NC/DOAR warning, or imposition of Civil Penalties, further action (i.e., injunction with further Civil Penalties) will be considered.

Unlike some FDA programs where the need for legal action may be triggered by a single violative inspection report or sample, legal action against x-ray assemblers is most frequently triggered by a pattern of violative field tests. Such a pattern of violation cannot routinely be detected by monitoring individual field tests or Notification letters. Special district record-keeping or use of the CDRH computer data base by the x-ray auditor will be needed for monitoring assembler noncompliance trends.

Recommendations for NC/DOAR warning letters will be reviewed by CDRH (HFZ-322). For assemblers installing less than 16 systems in the cited time frame (not to exceed two (2) years) civil penalties will be the enforcement choice when the conditions of CPG 7133.12 are met. Table 1, listed below will be used as criteria for noncompliance declarations.

TABLE I

No. Installed	No. Tested	No. Noncompliant	%NC
Less than 16	(refer to CPG 7133.12 paragraph B)		
16 to 25	5	2 or more	40
26 to 50	8	3 or more	37.5
51 to 90	13	4 or more	30.8
91 to 150	20	6 or more	30
151 to 280	32	8 or more	25

If the number tested exceeds the numbers listed in Table I, then the noncompliance rate must equal or exceed the percent NC rate listed in the table above. Should the number tested exceed 50 percent of the number installed, Civil Penalties may be the more advantageous approach. Any questions concerning this guidance should be referred to the Diagnostic Devices Branch.

4. Inspection Priorities

Inspections of diagnostic x-ray assemblers shall be initiated for the following reasons:

- To document the number and location of systems requiring coverage under the firm's corrective action plan (CAP) when noncompliance declaration has been issued.

- When preparing a civil penalty action against an assembler, to document responsibility for

violations.

- To obtain a listing of recent installations of certified x-ray equipment for further testing when developing a civil penalty case.

- When investigating product defects or accidental radiation occurrences.

- When investigating a failure to file an assembler report, form FDA 2579.

- When assembler reports, forms FDA 2579, are repeatedly late or repeatedly contain critical errors.

5. RRHR Management Activities

The RRHR will coordinate and supervise voluntary working agreements and agency contracts with states performing diagnostic x-ray field testing including:

- Arrange for states to submit the test data to the district auditor for review, calculations, and classification in accordance with Part III A.1.f.

- Arrange for states to contact the auditor by phone for all Class A deficiencies as soon as possible.

- Review any problem reported on the "blue copy" of the test form by the auditor and refer to the affected state, as appropriate.

- Maintain the "blue copy" of the test form in the state file.

* - Draft, renew, or provide changes to Partnership Agreements (PA) for Regional Food and Drug Director (RFDD) signature. Recommendations will be provided to Division of Federal State Relations HFC-150 and HFZ-322. Copies of final signed agreements will also be provided to HFC-150 and HFZ-322. Field tests that do not pass the FDA audit will not be credited toward the agreement number. *

- On request from the District Office, arrange with contract or partnership states to emphasize testing of installations by problem assemblers identified to them by FDA and to expedite submission of test results for those assemblers to assure timely follow-up action by FDA.

- Arrange for State follow-up field testing where State field test reports have determined that violative x-ray systems require correction and the district is unable to perform the required follow-up.

- Arrange for State follow-up of noncompliant x-ray systems that are determined to be the user's responsibility. If a State is unable to have the user correct a Class A timer non-termination violation, the RRHR shall arrange for district follow-up to document the violation for possible detention/seizure consideration.

- Arrange for qualified auditors to train State and FDA personnel to perform routine field tests.

- Arrange with the auditor for periodic joint field test audits of State or FDA personnel by a qualified auditor to insure that proper procedures and techniques are used in the collection of test data.

PART III - INSPECTIONAL

A. OPERATIONS

1. Field Testing

a. Test new fully certified x-ray systems, preferably within 3 months of and not later than 1 year after installation in accordance with specified CDRH test procedures (Reference 4).

b. Select test sites (concentrating on problem assemblers) based on information from:

(1) CDRH computer data base

(2) Copies of FDA 2579s sent to the district or State agency.

(3) Fully certified systems encountered at user facilities.

c. Schedule appointments in advance to insure availability of the x-ray system for testing. Arrange to have someone familiar with the x-ray system available to assist in its operation during the test.

d. At the test site:

(1) Wear personnel dosimeters (TLD badges) when performing tests.

(2) Issue a FDA 482 only when requested by the user. (Applies to FDA personnel only).

(3) Visually verify that the system is fully certified. If not fully certified, testing may only be performed if a major component is certified.

(4) Conduct the field test and complete the appropriate field test record (FTR) as instructed in FDA 81-8161.

(5) Document any x-ray system damage (real or claimed) due to the field test on form FD 2766, Claim for Damage to an Electronic Product. (Refer to Attachment F). Forward this form immediately through the RRHR to Office of Compliance HFZ-300 (Do not delay submission or attempt to refute the claimed damages).

NOTE: State survey personnel should immediately report damage to an x-ray system to the RRHR. The RRHR will determine what follow-up is required.

(6) Review the field test record for obvious items of noncompliance prior to leaving the test site. Class A items should be easily detected since most represent observations by the surveyor:

- Primary barrier interlock failure
- Timer non-termination

- Excessive entrance exposure rate (in excess of 25 R/Min)
- The primary beam extends beyond the edges of the primary protective barrier.

Attachment D provides the criteria for classifying items of noncompliance.

(7) For suspected Class A violations :

(a) -Advise the user immediately of the results and that:

- Routine use of the system should be discontinued until the problem is corrected.

- Operation of the system could be hazardous to the patient and/or operator.

- FDA will determine responsibility, notify the responsible party and the State, and effect correction.

(b) Telephone the auditor immediately and inform the auditor of the Class A condition.

(8) For suspected Class B violations advise the user of the results and that:

(a) The system may not comply with the Federal performance standard.

(b) FDA will confirm the compliance status of the system via computer data analysis.

(c) FDA will determine the responsibility for any items of noncompliance, notify the responsible party, and effect correction.

(9) For suspected Class C results, advise the user that computer calculations must be made to determine if the system is in compliance, and that:

(a) FDA will determine the compliance status of the system.

(b) If the system fails to comply, FDA will determine responsibility, notify the responsible party, and effect correction.

(c) FDA will send the facility a copy of any Notification letter which it issues.

(10) For suspected Class D results, advise the user that while computer calculations must be performed to determine compliance, the system appears to be fully compliant.

(11) Attempt to determine responsibility for any noncompliances before leaving the facility. (See Attachment N for further guidance).

e. Flag suspected Class A and Class B test records. A "SPECIAL" sticker should be affixed to the upper left corner of Class A test records to alert the auditor that the record has a suspected Class A result. A route slip or other suitable identifier with the designation "Class B" will suffice for suspected Class B results.

f. Route suspected Class A test records to the auditor immediately, suspected Class B records within 2 working days, and Class C or D records within 2 weeks after testing. Send the original, 1st copy, and blue copy to the accomplishing district auditor. Retain the yellow copy as a reference in the event the auditor has questions regarding the field test.

2. Auditor Activities

a. Quality Assurance Review

The accomplishing district auditor shall:

* (1) Ensure test data integrity by verifying the field test edit checks as specified in the CDRH test procedures manual (Reference 4). *

(2) Be responsible for timely field test data entry utilizing the XRAYAPSY system for CDRH computer calculation of test results.

(3) Review all calculated field test results from CDRH computer entry and,

- Return rejected FDA tests to the investigator's supervisor for appropriate action.

* - Return rejected state tests through the RRHR to the state. The RRHR will work with the state to achieve acceptable tests. Rejected tests will not count toward the state's agreement numbers.

*

(4) Classify all field test records in accordance with criteria in Attachment D, based on test results.

* (5) When the auditing of the record is completed, if the assembler is from a different district, forward the white copy of the field test record and a copy of the assembly report to the appropriate home district auditor. *

b. Evidence Development

The home district auditor shall:

(1) Make a thorough determination of responsibility for violations when recommendations for regulatory follow-up involving an assembler is being considered. This determination shall include at a minimum, the evaluation of all of the following factors which may be pertinent:

- field test data and calculated results

- responses to any Notification/user letters

- type of repair made to correct the violation (adjustment vs. component replacement)

- equipment maintenance schedule and maintenance history

- all past service repair records

- information gathered during assembler establishment inspections

Unless there is clear documentary evidence which demonstrates that violations are attributable to improper assembly, the assembler cannot be held responsible.

If the service report shows only adjustment of a component, there is presumed evidence of assembler error at installation. However, replacement of a defective component may indicate a manufacturer problem and is less convincing evidence of assembler responsibility. Additional evidence development by the auditor or by CDRH engineers may be necessary.

(2) Ensure that all field corrective actions of the home district are added to the CDRH data base with proper responsible party determination.

(3) Request assistance from the accomplishing district auditor in developing documentation and evidence needed for regulatory follow-up.

(4) Monitor field testing results, responses to Notification or Warning Letters, assembler EI's, follow-up field test data, etc., and identify assemblers for whom recommendations for regulatory follow-up should be considered. The auditor will prepare a referral memo describing the violations, evidence, and recommendation for appropriate action of civil penalty and/or assembler recall based on criteria specified in Part II.3 and CPG 7133.12.

(5) Review all Notification or Warning letters for completeness and accuracy prior to issuance.

c. Quality Assurance Audits

- Perform on site quality assurance audits of FDA and State personnel to assure their proficiency in conducting field tests of diagnostic x-ray units.

* - Each fiscal year, conduct at least two joint audits per person. Only personnel conducting at least 10 field tests per year will be joint audited. (See Field Management Directive No. 76 for further guidance). Audits shall be: *

- Joint field tests with the person being audited, or
- Follow-up retest of the same unit within 30 days of the initial test by the person being audited.

d. Training

Provide on-the-job training (OJT) for all new FDA and State surveyors consisting of the following number of x-ray field tests:

- NOTE: More than one person's name may appear on the field test record, however, the first name is the lead surveyor receiving credit for the survey.

*

Abovetable X-ray Source Radiographic and kVp (at least 3).

Undertable X-ray Source Fluoroscopic and Spot Film (at least 3).

C-Arm Fluoroscopic (at least 1).

Mobile (at least 1).

Prior to conducting the OJT, ensure that the trainee has viewed the CDRH videotapes on field test procedures.

e. Public Liaison

Deliver presentations, when requested, on aspects of the Diagnostic X-ray Standard before groups of radiation professionals such as radiologists, technologists, and physicists.

3. Review/Maintenance of FDA 2579, Report of Assembly of a Diagnostic (Medical) X-ray System

The home district of the assembler shall:

a. Maintain all originals of forms FDA 2579 for 3 years.

b. When there is evidence of a problematic assembler, in preparation for assembler inspection for cause, review FDA 2579 reports for errors. Items requiring correction should be indicated for discussion upon inspection.

(1) Minor Corrections involve items not affecting compliance (e.g., missing or incorrect date of assembly (block 3e) or incorrect identification of component model numbers) and can be corrected directly on the form after verification by assembler.

- Make the correction in red ink.

- Date and initial the form in the upper right hand corner.

(2) Major corrections involve:

- Failure of assembler to sign the form.

- Failure to enter the facility name, city, or state (block 1);

- No indication of what components were installed (blocks 4g and 4h).

c. For major corrections to the assembler form, have the assembler fill out a new form with instructions to:

- Complete the entire form.

- Return the white original to the district.

- Distribute the other copies as usual within 15 days.

- Indicate in the comments the form is a replacement for corrections to the original assembler form with number xxxx.

d. Upon receipt of a replacement original form from the assembler, review the white original. If it is correct:

- Initial and date the form in the upper right hand corner.

- Place a red sticker at the top of the white original, indicating the accession number of the old duplicate form. (This step is crucial in order for CDRH to locate and delete old duplicate information from the database.)

- Send the original to CDRH, HFZ-307 (CDRH will update the computer database and send the white original on to the appropriate installation district.)

e. For minor assembler form corrections:

- forward a copy of the form to CDRH HFZ-307
- indicate the corrections in red
- place a note or sticker to indicate the form has corrections.

The installation (accomplishing) district shall:

a. Maintain all originals of forms FDA 2579 for 1 year from date of installation for the purpose of selecting testing sites. After 1 year the form should be mailed to the assembler home district if it differs from the installation district, where it will be kept for 3 years after installation.

b. When a field test is conducted at an installation, attach the original copy of FDA 2579 to the home district copy of all field test records. After the field test record has passed the audit/edit criteria distribute the field test record with attached FDA 2579 to the appropriate home district office.

NOTE: For assembler reports of Dental x-ray equipment, the assembler shall mail the original white copy of the assembler report directly to the FDA district responsible for the installation site.

Any dental forms erroneously mailed by the assembler to CDRH will be forwarded to the installation district. Likewise, districts should forward to the correct installation district any

forms erroneously received in their office. CDRH does not maintain assembler forms for dental systems in the centralized data base.

All x-ray assembly reports will continue to be maintained by the responsible home district office for at least 3 years.

4. Assembler Inspections

Conduct inspections in accordance with Chapter 5 of the IOM and investigate these specific aspects of the assembler's operation:

a. Assembly and sales records - full review to determine if all installations have been reported.

b. Complaint files - look for evidence of accidental radiation occurrences, radiation defects, and noncompliances with the standard.

c. Repair records - determine if the assembler is charging users to correct items of noncompliance.

d. Test equipment and calibration - assembly of noncompliant systems may be due to use of improper test equipment or equipment which is out of calibration.

e. If the inspection is a follow-up to errors or non-submission of forms FDA 2579:

- discuss the reporting requirements with the assembler.

- explain how to complete the forms correctly.

- point out discrepancies encountered on the forms and leave copies for correction.

- instruct the assembler to resubmit corrected forms to the district within 10 days.

f. Determine responsibility for field test noncompliances by the review of installation and repair records.

5. Sample Collection - Collect documentary samples when noncompliance is suspected and documentary evidence is needed to support regulatory action. (see IOM 405.2). No physical samples will be collected under this program.

B. REPORTING BY THE ACCOMPLISHING DISTRICT AUDITOR

1. Suspected Class A Violative Field Tests

a. Confirm the suspected noncompliance is a Class A violation by consulting Attachment D of this compliance program.

b. Verify proper user notification by the surveyor, and if not done, immediately warn the user against use of the hazardous system.

c. If the assembler is suspected to be responsible for the violation, inform the assembler of the noncompliance by telephone and request correction. Document assembler notification.

d. Notify CDRH (see Part VI and Attachment C) and the RRHR within 2 working days.

e. When the above information is obtained by telephone response, follow-up to insure that receipt of the field test record is provided as soon as possible.

C. REPORTING BY THE HOME DISTRICT AUDITOR

Review the CDRH Field Correction Action Report (FCAR) and ensure that all updates are added to the CDRH data base.

CAUTION: Unless responsibility has been clearly determined, responsibility should be reported as "Not Determined." CDRH generally will not include in a legal action any test record for which the auditor determines the responsible party is other than the assembler.

Forward assembler responses which allege manufacturer responsibility for noncompliances to HFZ-300 for Center follow-up. Include all documentation necessary to support this conclusion.

D. AUDITING ASSEMBLER CORRECTIVE ACTIONS

The accomplishing district auditor shall arrange the following testing:

1. Within 10 working days following reported correction of all Class A violations.

2. Within 30 days following reported correction for at least 10 percent of the Class B violations.

Concentrate follow-up field tests more heavily for:

1. Assemblers who in the past have reported violative products to be corrected when in fact they were not, and

2. New assemblers with no established record of properly correcting violative products.

PART IV

No laboratory testing will be done under this program.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

A. REGULATORY PHILOSOPHY AND STRATEGY

Diagnostic x-ray equipment is regulated under both Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) and Subchapter A - Drugs and Devices of Chapter V of the Federal Food, Drug, and Cosmetic Act (FFDCA). Subchapter C provides authority to require product recalls for noncompliant or defective radiation-emitting electronic products. In addition, Subchapter A (as amended by the Safe Medical Devices Act) provides authority to require product recalls for medical devices that may cause a serious risk to health. (All diagnostic (medical) x-ray products are medical devices.) When there is a choice, regulatory/administrative action is preferred under Subchapter C, but both portions of the FFDCA may be used in conjunction for maximum effectiveness.

* The primary enforcement approach for generic/design related violations caused by the x-ray component manufacturer is mandatory recall (refer to RPM Chapter 7, Attachment F for details). The CDRH is responsible for initiating recalls by x-ray manufacturers and importers. For violations which are attributable to the assembler, the field maintains responsibility for enforcement. *

Since x-ray assembly is more of a customized operation in which widely varying random violations may occur, when a single system is discovered noncompliant (as with our routine compliance testing program), a product-wide recall or civil penalty action is not generally applicable. The primary assembler enforcement approach is issuance of a Notification letter requiring correction of the cited violations on the unit tested, followed by increased surveillance to establish a pattern of violation. Once a pattern of violations is determined (see TABLE I Part II and CPG 7133.12) then the district should either issue a noncompliance declaration with district ordered assembler recall (NC/DOAR) or pursue civil penalties to dissuade further violations.

When a pattern of performance standard violations has been documented, or the responses to Notification letters are unsatisfactory, or the firm fails to file form FD 2579 after being previously advised in writing of the consequences of continued failure to file, recommend appropriate action against the assembler as described in CPG 7133.12.

In the absence of evidence to the contrary, for violative x-ray systems found during field testing:

- the assembler is responsible if the unit was tested within one year of installation
- the user is responsible if the unit was tested more than one year after installation

Other relevant compliance policies, and mandatory recall, detention/seizure and civil penalty procedures are contained in:

- CPG 7133.12 (Regulatory Actions Against Assemblers Who Install Noncompliant Diagnostic X-ray Equipment.)
- CPG 7133.23 (Assessment of Civil Penalties Against Manufacturers and Importers of Electronic Products.)

- CPG 7133.25 (Detention/Seizure - Hazardous Diagnostic X-ray Systems, July 1, 1983.)

- CPG 7133.27 (Corrective Actions - Obligations of Factory-Based Manufacturers and Assemblers of Diagnostic X-ray Equipment under the performance standard for Diagnostic X-ray Equipment.)

- CPG 7133.28 (Regulatory Actions Against Assemblers of X-ray Equipment That Fail to File Reports of Assembly.)

- RPM Chapter 6 (Civil Penalties - Electronic Product Radiation Control)

- RPM Chapter 7, Attachment F (Recalls of Radiation-Emitting Electronic Products under Subchapter C Electronic Product Radiation Control)

B. CASE GUIDANCE

* Informal consultation with the Center at an early stage in the development of a regulatory action is encouraged in order to facilitate timely implementation of the action; contact the Chief, Diagnostic Devices Branch, HFZ-322, Phone: 301-594-4591. All necessary samples and other supporting documentation must be tabbed and their location cross-referenced in the recommendation in order to assist in a timely review.

1. Assembler Violations

Recommend radiation control civil penalties (see CPG 7133.12 for appropriateness) for:

- a pattern of violative field tests in accordance with Table I Part II B.3. and CPG 7133.12.

- a pattern of failure to provide FDA with required assembler reports meeting the criteria in CPG 7133.28.

- unsatisfactory responses to Notification letters or failure to correct noncompliant products.

- deliberate and willful violations.

- violations occurring when NC/DOAR action is not appropriate or adequate (see section D. below and Table I, Part II, B.3).

- the violation has resulted in serious injury or death.

Recommend medical device civil penalties as appropriate. Section 501(c) charges can be used if the field test shows one or more assembler related noncompliance for each unit.*

2. Manufacturer Violations

Refer all Class A or Class B noncompliant test records attributable to the x-ray system or component manufacturer to CDRH (HFZ-322) for evaluation and follow-up action. The referral

memo should include:

- A description of the noncompliance.

- Identity of the manufacturer(s) and model(s) involved.

- Reason for suspecting a manufacturer problem.

- Identity and date of any previous telephone contact with CDRH on the problem.

- Whether the unit has been corrected.

If the unit has not been corrected, CDRH will request correction by the manufacturer. If evaluation confirms a generic or design problem, CDRH will declare noncompliance and require correction/recall in accordance with RPM Chapter 7, Attachment F.

The home district will monitor approved corrective action programs (recalls). It may be appropriate to recommend civil penalties for failure to correct noncompliant products or for continuing or willful violations.

3. Detention/Seizure

Recommend detention/seizure for serious radiation hazards if the responsible firm (manufacturer or assembler) refuses to correct or is unable (e.g. out of business) to correct the hazard. Serious radiation hazards include the following or similar situations (see CPG 7133.25):

- Non-termination of the x-ray timer,

- Excessive entrance exposure rate on fluoroscopic units.

Direct reference authority is provided for seizure actions when an administrative detention action has previously been approved.

C. ISSUANCE OF NOTIFICATION LETTERS FOR NONCOMPLIANCE WITH THE STANDARD WHERE THE ASSEMBLER IS SUSPECTED TO BE RESPONSIBLE.

NOTE: All Notification letters should be reviewed by the home district auditor prior to issuance. Class A violations are issued as Warning Letters.

1. Assembly of Noncompliant Diagnostic X-ray Systems

a. Issue a Notification letter (see Attachment K) to the responsible assembler for Class A and Class B field test results obtained within one year of installation. Notification letters shall issue:

- Addressed to the most responsible individual at the local assembler firm.

- Warning of civil penalties in accordance with Chapter 6 of the Regulatory Procedures

Manual.

- Within 45 days of the field test (60 days for state tests).
- Within 2 days after receipt of results showing Class A violations.
- Within 10 working days after receipt of results showing Class B violations.
- Requesting assembler response within 15 working days after receipt for all Class A or within 30 working days for all Class B violations.
- Requesting a copy of the assembler service report (to help determine the cause of the violation and to assure correction at no cost to the user).
- With copies of the Notification letter in every case sent to:

  a) the user

  b) the x-ray or medical systems headquarters official responsible for the local assembler firm

  c) the x-ray control manufacturer's corporate headquarters officials identified in Attachment G. If the violative product is a beam limiting device (BLD), the BLD manufacturer's corporate headquarters official identified in Attachment G will receive a copy if different from the x-ray control manufacturer's firm.

  d) the home district auditor for review prior to issuance.

  e) the testing district auditor (if different from the home district).

  f) CDRH, HFZ-300.

  g) The State Radiological Health Agency

b. Evaluate the assembler's response and route a copy to the home district x-ray auditor for confirmation of responsibility, assessment of qualification for civil penalties recommendation, and completion of CDRH Field Correction Status Report.

c. Respond to refutations or exemption requests when the assembler exercises his rights under 21 CFR 1003.30. Obtain technical assistance from the auditor or CDRH personnel listed in Attachment B, if necessary.

d. Disapprove unsatisfactory corrective actions proposed or performed by assemblers.

e. If the assembler fails to provide a satisfactory or timely response, issue an assignment for follow-up field testing. If the violation is not corrected, consider regulatory action.

NOTE: When an assembler disagrees with Agency action, he may request a hearing under 21 CFR

16. If such a request is received by the district, contact HFZ-300 so that arrangements may be made to designate a hearing officer in accordance with 21 CFR 5.30(c).

2. Failure to Submit, Late Submission of, or Errors in the Submission of FDA 2579, Report of Assembly of Diagnostic X-ray Systems

Issue a Notification letter to the most responsible person at the local assembler's office (see Attachments H through J).

NOTE: Submission of a 2579 more than 30 days after assembly is considered late.

D. ISSUANCE OF WARNING LETTER, NONCOMPLIANCE DECLARATION AND DISTRICT ORDERED ASSEMBLER RECALL (NC/DOAR WARNING LETTER) FOR ASSEMBLER RESPONSIBLE NONCOMPLIANCES WITH THE STANDARD. (NOTE: All NC/DOAR letters should be reviewed by the home district auditor prior to issuance.)

1. Assembly of Noncompliant Diagnostic X-ray Systems

a. Issue a NC/DOAR warning letter (see Attachment P) to the responsible assembler in accordance with CPG 7133.12 and Table I of Part II. Address the letter to the most responsible individual at the local assembler firm. Copies of the NC/DOAR letter should be sent to the home district auditor, installation district auditor, the RRHR and HFZ-300.

b. Evaluate the assembler response using the guidance of Attachment Q. Full use of the home district auditor and contacts with the Diagnostic Devices Branch are advised to assist in the technical aspects of determining acceptable responses.

2. Monitoring Assembler Corrective Action Plans

When Notification letters are issued as follow-up to a violative routine field test, the assembler is not required to submit a corrective action plan (CAP) for the correction of the one individual unit. To require submission of a CAP for individual violations would prolong indefinitely the correction of violative products.

* Under the NC/DOAR action, FDA Districts will issue noncompliance declarations to specific assemblers, covering all assemblies of fully certified diagnostic x-ray systems assembled over a prescribed time period. Thus, it is essential that a CAP be submitted to, and monitored by, the assemblers home district. Monitoring begins when it is determined that the assembler has elected to submit a CAP in lieu of a refutation or exemption request. Review of the technical aspects of the CAP should be the responsibility of the home district x-ray auditor. If assistance is needed, the auditor should contact the Diagnostic Devices Branch (HFZ-322) at (301)-594-4591. Guidance for evaluating assembler responses can be found in Attachment Q. *

Assembler CAPs are to be handled as recalls. The procedures for handling recalls are detailed in the Regulatory Procedures Manual (RPM), Chapter 7. Attachment F of the RPM provides specific guidance for x-ray assemblers.

The home district should incorporate the following steps as part of the CAP monitoring:

a. Upon receipt of a CAP, prepare the Recall Alert described in the RPM.

b. Schedule an establishment inspection of the assembler to obtain additional details of the CAP. During this inspection, the investigator should obtain the information necessary for submitting a Recall Recommendation.

Note: The district should allow the assembler up to 30 days to formulate a complete CAP and to submit it in writing. Delay submitting the Recall Recommendation until this information is received. Although the Regulations do not require FDA to provide the assembler with this 30-day grace period, additional time should be permitted to prepare a complete CAP since the CAP submission by an assembler has not normally been required.

c. If there will be a delay in obtaining complete details of a CAP, advise the assembler that he must provide interim purchaser notification pursuant to 21 CFR 1003.21. A model letter to purchasers is included as Attachment R.

d. Once a complete CAP is received, the district x-ray auditor should review the CAP, and if acceptable, prepare a CAP approval letter (Attachment S) for the signature of the District Director.

* e. Copies of the CAP approval letter should be sent to the Diagnostic Devices Branch (HFZ-322). *

f. The Diagnostic Devices Branch, DOE I, OC, CDRH will assign the recall number, recall strategy, and recall classification as directed in the RPM.

g. Upon receipt of the recall number, strategy, and classification by CDRH, the district will prepare the recall notification.

h. The district will also, upon receipt of the recall information from CDRH, prepare a notification letter to the recalling firm setting forth the Agency's position regarding the recall. Include instructions for submitting monthly progress reports, if not included in the CAP approval letter.

i. Once the assembler reports completion of the CAP, the district can begin to schedule audit checks at purchaser locations as assigned by CDRH in the Recall Strategy Statement. Audit checks should be performed within six months of the date of correction by the assembler and should consist of a complete field test of the system utilizing the appropriate field test method. The focus of the audit checks should be on the noncompliances cited in the original Warning Letter. Under some circumstances when the recall takes longer than 6 months, an audit check can begin before the completion of the CAP on all locations (see RPM Chapter 7 Attachment F). Generally audit checks are performed on 10% of the product under recall.

j. The recall should be declared effective if all audit checks demonstrate full compliance with the elements of the Performance Standard cited in the original Warning Letter. Prepare a Recall Termination Recommendation at that time.

Note: Since the number of audit checks will normally be small, a decision regarding the effectiveness will not be made if only one of the audited units fails to comply. A second series of audit checks should be conducted at purchaser locations, using the sampling criteria of ANSI/ASQ Z1.4. An identical number of units should be audited in both the first series and second series of audit checks. If the second series of the audit checks reveals no noncompliances, then the recall is effective. The recall shall be considered ineffective if during the first series of audit checks, more than one unit fails to comply with the Performance Standard as cited in the original Warning Letter, or, if during the second series of audit checks, one or more units fail to comply.

k. Whenever an audit check detects an item of noncompliance (covered by the CAP) that has not been corrected, issue a Notification letter to the assembler. If two or more such noncompliant systems are encountered which are assembler related (not caused by user abuse or failed component), prepare a recommendation for civil penalty.

Note: CDRH will not consider for inclusion in a civil penalty case any noncompliance for which the responsible party is identified as other than the assembler. The Field Corrective Action Report must identify the assembler as the responsible party.

3. Preparing the Recall Alert

In preparing the 24-hour recall alert (Attachment A of RPM Chapter 7), the following standard responses should be used:

a. Product - All assemblies of certified diagnostic x-ray systems performed between _____and _____.

b. Code - All makes and models, including _____ and _____.

c. Recalling Firm - List the names and address of the assembler.

d. Reason for Recall - Field test data collected by the FDA establishes that the recalling firm was routinely assembling certified diagnostic x-ray systems which failed to comply with the Performance Standard. The district issued a noncompliance declaration letter dated _____. The assembler responded with a CAP dated _____.

e. District Follow-Up - Include plans for any follow-up establishment inspection and whether or nor the CAP appears complete.

f. Date district learned of recall - Date of CAP letter from the assembler.

g. Recall initiation date - the date the CAP is received in the home district.

4. Preparing the Recall Recommendation

a. Product - Certified diagnostic x-ray systems assembled by _____ between _____ and _____. The products are used on a daily basis for

diagnostic radiology. All units are involved in this corrective action plan.

b. Code - Various

c. Recalled By & How - The assembler, _____, will test all systems for compliance with the Performance Standard, making the necessary corrections to bring each system into compliance.

d. Manufacturer - Products are assembled by the recalling firm using certified diagnostic x-ray components from a variety of manufacturers.

e. Date of recall - The date of the CAP. Since the CAP approval letter has not been issued, this is the date of the assembler response to the noncompliance declaration.

f. Reason - As described in Attachment A.

g. Distribution - Self explanatory.

h. Quantity - The number of certified x-ray systems covered by the CAP.

i. Current Status - Recall not started; Cap must be approved.

E. ISSUANCE OF INFORMATION LETTERS FOR USER CAUSED VIOLATIONS AND REFERRAL TO STATE AUTHORITIES

1. Issue information letters to users when field test results are obtained more than one year after installation and/or violations cannot be determined to be the fault of the manufacturer or assembler (see Attachment M). Send copies to the appropriate state radiation control authorities, the assembler, the component manufacturer, the RRHR for State coordination, the home district auditor, the installation district auditor, and HFZ-300.

2. If the user fails to respond, notify state authorities and the RRHR and request their assistance in obtaining correction. Also request state assistance to prevent use of a Class A violative product until it is corrected. If the state is unable or unwilling to gain compliance:

   - For non-termination of the x-ray timer only, consider detention/seizure in accordance with CPG 7133.25.

   - For all other Class A violations, contact HFZ-300.

   - For Class B violations, do not pursue the matter further.

3. Advise the home district auditor of all final actions or failures to obtain correction so that the Field Corrective Action Report (FCAR) may be completed.

F. FEDERAL/STATE RELATIONS

The RRHR will coordinate and supervise voluntary working agreements, agency contracts and/or Partnership Agreements (PA) with states performing diagnostic x-ray field testing.

PART VI - REFERENCES, ATTACHMENTS AND PROGRAM CONTACTS

A. REFERENCES

1. Title 21 Code of Federal Regulations, Subchapter J. Radiological Health.
2. Subchapter C Electronic Product Radiation Control of Chapter V of the Federal Food, Drug, and Cosmetic Act.
3. FDA Regulatory Procedures Manual, Chapter 7, Attachment F and Chapter 6.
4. BRH "Routine Compliance Testing for Diagnostic X-ray Systems or Components of Diagnostic X-ray Systems to which 21 CFR Subchapter J is Applicable", Revised December 1980, DHEW Publication (FDA) 81-8161.
5. Office of Radiological Health, Division of Compliance, Assemblers Guide to Diagnostic X-ray Equipment. (Rockville, Maryland).
6. United States Code, Title 21, Federal Food, Drug, and Cosmetic Act, As Amended
7. Compliance Policy Guide 7133.12, Regulatory Actions Against Assemblers Who Install Noncompliant diagnostic x-ray equipment.
8. "Calculation Programs for Routine Compliance Testing of Diagnostic X-ray Systems".
9. Compliance Policy Guide 7133.23, Assessment of Civil Penalties Against Manufacturers and Importers of Electronic Products.
10. Compliance Policy Guide 7133.25, Hazardous Diagnostic X-ray Systems.
11. Investigations Operations Manual (IOM).
12. Compliance Policy Guide 7133.27, Obligations of Factory-based Manufacturers and Assemblers of Diagnostic X-Ray Equipment Under the Performance Standard for Diagnostic X-Ray Equipment.
13. Compliance Policy Guide 7133.28, Regulatory Actions Against Assemblers of X-Ray Equipment that Fail to File Reports of Assembly.

B. ATTACHMENTS

1. Attachment A - List of CDRH, MEB, Personnel to Contact on Procurement, Maintenance and Repair of Instrumentation.
2. Attachment B - List of CDRH Personnel to Contact on Test Procedures, Use of Instrumentation, and Data Entry Problems.
3. Attachment C - General Communications List.

4. Attachment D - Classification of Items of Noncompliance and Defects.

5. Attachment E - Sample Report of Assembly of a Diagnostic X-ray System (FDA-2579).

6. Attachment F - Form FD-2766 Claim for Damages to Electronic Products.

7. Attachment G - Contacts for Manufacturers of Diagnostic X-ray Systems Controls.

8. Attachment H - Notification letter to the Assembler (Incomplete or incorrect FDA-2579 Report of Assembly).

9. Attachment I - Notification letter to Assembler - Standards Violation Found During Review of FDA-2579's or Records Review at the Assembler.

10. Attachment J - Notification letter to the Assembler (Failure to File FDA-2579 Report of Assembly).

11. Attachment K - Notification letter to the Assembler. (Notification of Defect or Noncompliance on FD-2786 Field Test).

12. Attachment L - Field Correction Status Report

13. Attachment M - Notification Letter to the User (Notification of Noncompliance Attributable to User Actions or Inaction).

14. Attachment N - Responsibility for Defects or Noncompliances.

15. Attachment O - Listing of Qualified X-ray Auditors

16. Attachment P - Sample Warning letter-Noncompliance Declaration With District Ordered Assembler Recall Letter to X-ray Assemblers.

17. Attachment Q - Guidance for Evaluating an Assembler Response to a Noncompliance Declaration With District Ordered Assembler Recall Letter.

18. Attachment R - Sample User Notification Letter for Assembler Noncompliances and CAPs.

19. Attachment S - Sample CAP Approval Letter to X-ray Assemblers.

C. PROGRAM CONTACTS

1. CDRH Contact - Questions concerning this compliance program should be directed to the Field Programs Branch, Division of Program Operations, Office of Compliance, CDRH, telephone number (301) 594-4695. Secondary contact may be made with individuals listed on Attachment C.

* 2. ORA Contact - The ORA Headquarters contact for this compliance program is ORO/DEIO (HFC-132), Liliane Brown, telephone number (301)-827-5632. *

PART VII - CENTER RESPONSIBILITIES

A. The CDRH shall:

1. Monitor nationwide noncompliance trends for different types of x-ray systems and for various plant based x-ray manufacturers.

2. Declare noncompliance and require product recall by manufacturers where nationwide field test data indicates a noncompliance rate well above the national average, or where design related generic violations are identified.

3. Provide calibrated test equipment for use by FDA and state inspectors.

4. Develop computer listings of all certified models of diagnostic x-ray components and systems (Manufacturers Model List) and provide these to each Region and District.

5. Routinely provide listings of problem assemblers for concentrated field testing and enforcement action.

6. Provide periodic status reports on assembler noncompliance trends, and special reports on request by the District.

7. Maintain/develop computer software for direct access to CDRH computer data by Auditors and District DPU's.

8. Date-stamp assembler reports (FDA-2579) as received, enter the data into the data base, and mail forms to the appropriate accomplishing district investigations branch weekly for review for testing selections.

9. Recommend specific sites for special tests when necessary. Survey forms and special test procedures will be provided by the Office of Compliance. Portable test equipment will be supplied if needed by the Office of Science and Technology.

10. Provide the field with information concerning system and component manufacturers corrective action plans. This information will include procedures for monitoring these plans. Advise the field of legal opinions, including those compliance cases, and advisory opinions which impact on their responsibilities in dealing with assemblers.

11. Provide the field with a listing of unresolved noncompliances on a routine basis (Field Correction Status Report) and provide a procedure for each district to monitor their status of unresolved noncompliances.

12. Provide originals of all FD 2579 reports of assembly to the installation district.

13. Monitor and evaluate all test records, assignments, and correspondence relating to this program to

identify trends or problems with the program.

14. Resolve specific program problems with the district office or ORA as soon as they are identified.

B. Program Evaluation - Within 3 months after receipt of all documentation for the fiscal year, an informal evaluation will be conducted to review the results of this program and any needed improvements to increase program effectiveness. No formal written evaluation report will be prepared unless requested by the Director, Office of Compliance.

Compliance Program Guidance Manual: Field Compliance Testing of Diagnostic (Medical) X-ray Equipment.[1]

[1]This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

LIST OF CDRH, MEDICAL ELECTRONIC BRANCH PERSONNEL TO CONTACT ON PROCUREMENT MAINTENANCE AND REPAIR OF INSTRUMENTATION

All requests for repair or replacement of instrumentation should be made through the instrumentation "HOT LINE" (30l) 443-l736. This phone will be manned 24 hours a day by either CDRH, MEB, personnel or a recorder. If answered by the recorder, the call will be returned if you leave your name and telephone number. Frank Cerra HFZ-135, telephone (30l) 443-2536 ext 23, is coordinator of field support activities and is the primary contact for questions which cannot be resolved on the "HOT LINE".

The following is a list of individuals most familiar and able to answer questions regarding the specifically listed equipment. Their telephone number is (30l) 443-2536 except as noted.

EQUIPMENT	CONTACT
Test Stand and Supplies	Elizabeth Rodgers Martha Kester
G-M Survey	Frank Cerra
MDH Survey Meter	Elizabeth Rogers
Digaphot	Frank Cerra

DO NOT return instruments to headquarters for calibration or repairs until calling the "HOT LINE" or the appropriate individual and thus obtaining instructions for return.

CDRH, OC PERSONNEL TO CONTACT ON TEST

PROCEDURES AND USE OF INSTRUMENTATION

	COMMERCIAL TELEPHONE	FAX NUMBER
l. Henry Knox	30l-594-4591	301-594-4636
2. Tom Jakub	301-594-4591	301-594-4636

CDRH PERSONNEL TO CONTACT FOR

COMPUTER DATA ENTRY PROBLEMS

1. Henry Knox	301-594-4591	301-594-4636	
* 2. Scott Lowe	301-827-4555 ext 102	301-827-5192	*

GENERAL COMMUNICATIONS LIST

	COMMERCIAL TELEPHONE	FAX NUMBER
1. Henry Knox	301-594-4591 ext 161	301-594-4636
2. Wes Morgenstern	301-594-4699	301-594-4715
3. Thomas Jakub	301-594-4591 ext 151	301-594-4636
4. Marje Hoban	301-594-4695	301-594-4715
5. Director Office of Compliance	301-594-4692	301-594-4610

CLASSIFICATION OF ITEMS OF NONCOMPLIANCE AND DEFECTS

Class A

Conditions which may pose a serious radiation hazard to the public health and safety.

l. An x-ray system having a malfunction such that inadvertent exposures could occur e.g., a system such that when the exposure switch is activated, not one but repeated exposures occur, or the timer fails to terminate exposure, or exposure initiated without utilizing the exposure switch.

2. A fluoroscopic x-ray system with an entrance exposure rate of greater than or equal to 25 R/min. , except:

   (a) During recording of fluoroscopic images, or

   (b) When an optional high level control is activated. If the control was manufactured after May 1995, the high level entrance exposure rate is limited to 20 R/min and any reading exceeding 25 R/min is also a Class A violation.

3. A fluoroscopic system such that the entire x-ray beam is not intercepted by the primary protective barrier.

4. A fluoroscopic system such that x-ray production is possible when the primary protective barrier is not in position to intercept the beam.

Class B

Certified Systems and Components Only

These are conditions that (1) would result in a large amount of unnecessary radiation exposure during a routine diagnostic x-ray examination, or (2) indicate other clearly defined items of noncompliance (certified systems and components only). These conditions may be determined in the field and calculated as in Reference 4 (the Routine Compliance Test Manual). For purposes of regulatory follow up, Class B conditions are divided into four groups according to the degree of health hazard presented by the conditions. The groupings are: Substantial Hazard, Moderate Hazard, Low Hazard, and Minimal Hazard (as compared to a fully compliant x-ray system).

Substantial Hazard

1. An exposure rate beyond the plane of the image receptor, due to transmission through the primary protective barrier of a fluoroscopic x-ray system (with the attenuation block in the useful beam) of greater than or equal to 10 mR/hr for each R/min of entrance exposure rate at 10 cm from any accessible surface of the fluoroscopic imaging assembly.

2. An image-intensified fluoroscopic x-ray system such that the total misalignment of the edges of the x-ray field with the respective edges of the visible area of the visually defined field in the plane of the image receptor is greater than 10 percent of the SID.

3. A spot film device such that the total misalignment of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, exceeds 10 percent of the SID.

4. A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by greater than 10 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

5. Mobile radiographic systems where the illuminance of the light localizer is less than 96 lux at a 100 centimeter measurement distance.

Moderate Hazard

l. For radiographic x-ray systems:

   a. A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by greater than 5% of the SID and that the sum of the length and width differences without regard to sign be greater

than 7% of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

b. A radiographic x-ray system providing means to align the center of the x-ray field with respect to the center of the image receptor and the misalignment is greater than or equal to 5 percent of the SID.

c. A radiographic x-ray system providing means for visually defining the perimeter of the x-ray field and the total misalignment of the edges of the visually defined field is greater than 5 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is indicated to be perpendicular to the axis of the x-ray beam.

d. A coefficient of variation greater than or equal to 0.10 for a sample set of ten exposures as described in Reference 4.

e. A half-value layer more than 1/2 mm aluminum below the appropriate value listed in 21 CFR 1020.30 Table I.

f. Systems equipped with positive beam limitation where at SIDs for which the device is designed to operate, it does not either cause automatic adjustment of the x-ray field to the image receptor size in the plane of the image receptor within 5 seconds after insertion of the image receptor; or if adjustment is accomplished automatically in a time interval greater than 5 seconds, or manually, does not prevent the production of x-rays until such adjustment is made.

g. An average light localizer illuminance of less than 96 lux for stationary systems and between 96 and 144 lux for mobile systems, as measured with a Digiphot at a measurement distance of 100 centimeters or the maximum SID, whichever is greater.

h. A capacitor storage system such that the standby radiation is greater than or equal to 25 mR/hr.

i. A measured kilovoltage greater or less than the manufacturer's upper or lower accuracy limits:

(1) Measured kilovoltage greater than the indicated kilovoltage A measured kilovoltage more than 105 percent of the manufacturer's upper accuracy limit for indicated kilovoltage.

(2) Measured kilovoltage less than the indicated kilovoltage A measured kilovoltage that is less than 95 percent of the manufacturer's lower limit for indicated kilovoltage.

j. Intraoral dental systems capable of operation in the above 50 kVp range which exhibit a minimum source to skin distance less than 16 centimeters.

k. Intraoral dental systems capable of operation in the above 50 kVp range for which the field size at the cone tip is greater than or equal to 9 centimeters.

l. Dental radiographic systems in which it is possible to produce x-rays with the timer in the zero or off position.

m. Mammographic x-ray systems in which the edge of the x-ray field at the chest wall extends beyond the edges of the image receptor by more than 5 percent of the source to image receptor distance.

2. For fluoroscopic x-ray systems:

a. An image-intensified fluoroscopic x-ray system such that the total misalignment of the edges of the x-ray field with the respective edges of the visually defined field in the plane of the image receptor is equal to or greater than 6 percent, but less than 10 percent of the SID, and the sum, without regard to sign, of the misalignment along any two orthogonal dimensions intersecting at the center of the visible area of the image receptor is equal to or greater than 8 percent of the SID.

b. A nonimage-intensified fluoroscopic system such that any dimension of the x-ray field extends beyond the visible portion of the image receptor by greater than 8 percent of the SID.

c. For conditions described in 21 CFR 1020.32(d), if the maximum allowable entrance exposure rate is 5 R/min., test values of greater than or equal to 5.6 R/min., but less than 25 R/min. Correspondingly, for a maximum allowable rate of 10 R/min., test values of greater than or equal to 11.5 R/min. but less than 25 R/min. are included.

d. Half-value layer values which are more than 1/2 mm below the value specified in 21 CFR 1020.30 Table I.

e. An exposure rate due to transmission through the primary protective barrier of a fluoroscopic system with the attenuation block in the useful beam of greater than or equal to 4 mR/hr but less than 10 mR/hr for each R/min of entrance exposure rate at 10 cm beyond the plane of the image receptor.

f. A spot film device such that the total misalignment of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, exceeds 6 percent, but is less than 10 percent of the SID. The sum without regard to sign of the misalingment along any two orthogonal dimensions exceeds 7 percent of the SID.

g. Stationary fluoroscopes with a minimum source-to-skin distance of less than 35.2 centimeters.

h. Mobile fluoroscopes with a minimum source-to-skin distance of less than 27.2 centimeters or 18.1 centimeters when configured for surgical use (e.g. spacer removed).

i. For controls manufactured after May 1995, which have high level controls limited to 20 R/min, test values of greater than 21.5 R/min but less than 25 R/min.

j. Other similar situations.

Low Hazard

1. For radiographic x-ray systems:

   a. A coefficient of variation greater than or equal to 0.084 for a sample set of four exposures, or between 0.06 and 0.10 for a sample set of ten exposures as described in Reference 4.

   b. A linearity value of greater than or equal to 0.153. This value is based upon two sample sets of at least four exposures each, as described in Reference 4.

   c. A radiographic x-ray system having indicated field size dimensions such that aperture adjustments result in x-ray field dimensions that differ from those of the image receptor by equal to or greater than 5 percent of the SID when the beam axis is intended to be perpendicular to the plane of the image receptor.

   d. A stationary general purpose radiographic x-ray system (i.e., one equipped with stepless adjustment of the size of the x-ray field) such that the actual SID differs from the indicated SID by more than 5 percent of the indicated SID. These values are based on a test procedure using a direct measurement of the distance from the focal spot to the tabletop and from the tabletop to the film plane as described in Reference 4.

   e. For stationary systems only, an average light localizer illuminance of between 96 and 144 lux as measured with a Digiphot.

   f. A capacitor storage radiographic system such that the standby radiation is greater than 3.0 mR/hr, but less than 25 mR/hr.

   g. Systems equipped with positive beam limitation devices which do not allow the field size to be reduced to a size less than that of the image receptor.

   h. Systems equipped with positive beam limiting devices which do not provide for an automatic return to PBL from a reduced field size.

   i. Mobile radiographic systems for which the minimum source to skin distance is less than 27.5 centimeters.

* j. Mammographic systems for which the edges of the x-ray field on any side extend beyond the edge of the image receptor by more than 5 percent of the SID. *

   k. (1) When the maximum operating range is above 70 kVp; A half-value layer (HVL) between (0.15 + 0.04 x HVL) mm and 0.5 mm aluminum below the appropriate value listed in 21 CFR 1020.30 Table I.

(2) When the maximum operating range is 50 to 70 kVp: A half-value layer (HVL) between (0.08 + 0.04 x HVL) mm and 0.5 mm aluminum below the appropriate value listed in 21 CFR 1020.30 Table I.

(3) When the maximum operating range is less than 50 kVp: A half-value layer (HVL) between 0.1 mm and 0.5 mm aluminum below the appropriate value listed in 21 CFR 1020.30 Table I.

l. Systems equipped with positive beam limitation, which do not prevent the production of x-rays at SID's greater than 36 inches where the PBL device is not intended to operate.

2. For fluoroscopic x-ray systems:

a. Fluoroscopic systems equipped with high level control which do not provide an audible indication of the activation of the high level control.

b. Half-value layer (see item k(1) under radiographic systems).

* c. Systems which do not provide either continuous audible signal or termination of x-rays at the completion of a previously selected time interval. *

Class B

Uncertified Systems and Components Only

Other situations similar to those of Class B certified systems and components which in the judgement of the auditor constitute a defect as defined in 21 CFR 1003.2(b).

Class C

Certified Systems and Components Only

These are conditions that indicate test results exceeding the requirements of the standard but less than the values for Class B noncompliances for certified systems and components only. These may be determined in the field and calculated as in Reference 4.

l. For radiographic x-ray systems:

a. A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by 3.00 to 4.99 percent of the SID and that the sum of the length and width differences without regard to sign be between 4.00 and 6.99 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

b. A radiographic x-ray system providing means to align the center of the x-ray field with respect to the center of the image receptor and misalignment is between 2.00 and 4.99 percent of the SID.

c. A radiographic x-ray system providing means for visually defining the perimeter of the x-ray field and the total misalignment of the edges of the visually defined field is between 2.00 and 4.99 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is indicated to be perpendicular to the axis of the x-ray beam.

d. A radiographic x-ray system having indicated field size dimensions such that aperture adjustments result in x-ray field dimensions that differ from those of the image receptor by between 2.00 and 4.99 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

e. A stationary radiographic x-ray system providing means for stepless adjustment of the size of the x-ray field such that the actual SID is either larger or smaller than the indicated SID by between 2.00 and 4.99 percent. These values are based on a test procedure using direct measurement of the distance from the focal spot to the tabletop and from the tabletop to the film plane as described in Reference 4.

f. A coefficient of variation greater than 0.050 but less than 0.084. This value is based upon a sample set of four exposures. When a set of ten exposure values is made, the upper limit is reduced from 0.084 to 0.06 (see Reference 4).

g. Linearity value of greater than 0.100 but less than 0.152. This value is based upon two sample sets of at least four exposures each, as described in Reference 4.

h. (l) When the maximum operating range is above 70 kVp: A half-value layer (HVL) below the appropriate value listed in 21 CFR 1020.30 Table I but less than (0.15 + 0.04 X HVL) mm Al below the listed value.

(2) When the maximum operating range is 50 to 70 kVp: A half-value layer below the appropriate value listed in 21 CFR 1020.30 Table I but less than (0.08 + 0.04 X HVL) below the listed values.

(3) When the maximum operating range is less than 50 kVp: A half-value layer (HVL) below the appropriate value listed in 21 CFR l020.30 Table I but less than 0.1 mm Al below the listed value.

i. An average light localizer illumination greater than 144 but less than 160 lux as measured with a Digiphot.

j. A capacitor energy storage radiographic system such that the standby radiation is greater than 2.0 mR/hr but less than 3.0 mR/hr.

k. A measureable kilovoltage greater or less than manufacturer's upper or lower accuracy limits.

(l) Measured kilovoltage greater than indicated kilovoltage A measured kilovoltage ranging from the manufacturer's upper accuracy limit to a measured kilovoltage such that 95 percent of this value is greater than the upper accuracy limit.

Example: The indicated kilovoltage on the x-ray control is 100 kVp. If the manufacturer states an accuracy of ± 10 percent, the upper and lower accuracy limits would be 110 kVp and 90 kVp, respectively. In this case, a measured kilovoltage ranging from 110 kVp to 115.8 kVp would be a Class C noncompliance.

(2) Measured kilovoltage less than indicated kilovoltage A measured kilovoltage ranging from the manufacturer's lower accuracy limit to a measured kilovoltage such that 105 percent of this value is less than the lower accuracy limit.

Example: The indicated kilovoltage on the x-ray control is 100 kVp. If the manufacturer states an accuracy of ± 10 percent, the upper and lower accuracy limits would be 110 kVp and 90 kVp, respectively. In this case, a measured kilovoltage ranging from 90 kVp to 85.7 kVp would be a Class C noncompliance.

2. For fluoroscopic x-ray systems:

a. An image-intensified fluoroscopic x-ray system such that the total misalignment of the edges of the x-ray field with the respective edges of the visible area of the visually defined field in the plane of the image receptor is greater than 3 percent but less than 6 percent of the SID, and the sum, without regard to sign, of the misalignment along any two orthogonal dimensions intersecting at the center of the visible area of the image receptor is greater than 4 percent but less than 8 percent of the SID.

b. A nonimage-intensified fluoroscopic system such that any dimension of the x-ray field extends beyond the visible portion of the image receptor but by less than 8 percent of the SID.

* c. For conditions described in 21 CFR l020.32(d), if the maximum allowable entrance exposure rate is 5 R/min., test values of greater than 5.0 R/min., but less than 5.6 R/min. Correspondingly, if the maximum allowable entrance exposure rate is 10 R/min., test values of greater than 10.0 R/min. but less than 11.5 R/min. are included. *

d. Half-value layer (see h(1) under radiographic x-ray systems this section).

e. An exposure rate due to transmission through the primary protective barrier of a fluoroscopic system with the attenuation block in the useful beam of greater than 2.0 mR/hr but less than 4.0 mR/hr for each R/min. of entrance exposure rate at 10 cm beyond the plane of the image receptor.

f. A spot film device such that total misalignment of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, is greater than 3 percent but less than 6 percent of the SID. The sum without regard to sign of the misalignment along any two orthogonal dimensions is greater than 4 percent but less than 7 percent of the SID.

g. For controls manufactured after May 1995 which contain high level controls, where the maximum allowable entrance exposure rate is 20 R/min, test values greater than 20 R/min, but less than 21.5 R/min.

h. Stationary fluoroscopes with a minimum source-to-skin distance between 35.2 centimeters and 38 centimeters.

i. Mobile fluoroscopes with a minimum source-to-skin distance between 27.2 centimeters and 30 centimeters or between 18.1 centimeters and 20 centimeters when configured for surgical use (e.g. spacer removed).

j.

k. Other similar situations.

Class C

Uncertified Systems and Components Only

Other situations similar to those of Class B certified systems and components which in the judgment of the auditor meet the definition of 21 CFR 1003.2(b).

Class D

All items which indicate a system in compliance.

*

Class E

These items are minor functional noncompliances which may not be assembler related. They do not warrant a Notification letter by themselves, but may be included in a Notification letter issued because of other violations (similar to notification of Class C violations).

Minimal Hazard

1. For radiographic systems:

    a. Stationary systems where there are no means to indicate when the beam axis is perpendicular to the plane of the image receptor.

    b. Stationary systems where means are not provided to center the diagnostic source assembly over the image receptor.

    c. Systems where technique factors are not indicated at the operator's position.

    d. Systems which lack a warning label.

2. For fluoroscopic systems:

    a. No warning label present on the master x-ray control panel.

    b. Systems where the tube potential and tube current are not continuously indicated during x-ray exposure.

*

FOR FDA USE ONLY	DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service FOOD AND DRUG ADMINISTRATION **REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM**	Form Approved: OMB No. 0910-0213. Expiration Date: March 31, 1998 See Reverse for OMB statement **D**

1. EQUIPMENT LOCATION

a. NAME OF HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED		
b. STREET ADDRESS		
c. CITY	d. STATE	
e. ZIP CODE	f. TELEPHONE NUMBER ( )	

2. ASSEMBLER INFORMATION

a. COMPANY NAME		
b. STREET ADDRESS		
c. CITY	d. STATE	
e. ZIP CODE	f. TELEPHONE NUMBER ( )	

3. GENERAL INFORMATION

a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE *(Check appropriate box(es))*

- ☐ NEW ASSEMBLY-FULLY CERTIFIED SYSTEM
- ☐ REASSEMBLY-FULLY CERTIFIED SYSTEM
- ☐ REASSEMBLY-MIXED SYSTEM *(Both certified and non-certified components)*
- ☐ REPLACEMENT COMPONENTS IN AN EXISTING SYSTEM
- ☐ AN ADDITION TO AN EXISTING SYSTEM

b. INTENDED USE(S) *(Check appropriate box(es))*

☐ GENERAL PURPOSE RADIOGRAPHY	☐ UROLOGY	☐ CT WHOLE BODY SCANNER	☐ RADIATION THERAPY SIMULATOR
☐ GENERAL PURPOSE FLUOROSCOPY	☐ MAMMOGRAPHY	☐ HEAD-NECK *(Medical)*	☐ C-ARM FLUOROSCOPIC
☐ TOMOGRAPHY *(Other than CT)*	☐ CHEST	☐ DENTAL-INTRAORAL	☐ DIGITAL
☐ ANGIOGRAPHY	☐ CHIROPRACTIC	☐ DENTAL-CEPHALOMETRIC	☐ BONE MINERAL ANALYSIS
☐ PODIATRY	☐ CT HEADSCANNER	☐ DENTAL PANORAMIC	☐ OTHER *(Specify in comments)*

c. THE X-RAY SYSTEM IS *(Check one)*	d. THE MASTER CONTROL IS IN ROOM	e. DATE OF ASSEMBLY
☐ STATIONARY ☐ MOBILE		(mo.) (day) (yr.)

4. COMPONENT INFORMATION *(If additional space is needed for this section use another form, replacing the preprinted number with this Form Number, and complete Items 1, 4, and 5 only)*

a. THE MASTER CONTROL IS	b. CONTROL MANUFACTURER	d. CONTROL SERIAL NUMBER	e. DATE MANUFACTURED
☐ A NEW INSTALLATION ☐ EXISTING *(Certified)* ☐ EXISTING *(Non-certified)*	c. CONTROL MODEL NUMBER	f. SYSTEM MODEL NAME *(CT Systems Only)*	

Complete the following information for the certified components listed below which you installed. For beam limiting devices, tables and CT gantries enter the manufacturer and Model number in the indicated spaces. For other certified components, enter in the appropriate blocks how many of each you installed in this system.

g. SELECTED COMPONENTS			
BEAM LIMITING DEVICE	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
TABLES	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
CT GANTRY	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED

h. OTHER CERTIFIED COMPONENTS *(Enter number of each installed in appropriate blocks.)*

☐ X-RAY CONTROL	☐ CRADLE
☐ HIGH VOLTAGE GENERATOR	☐ FILM CHANGER
☐ VERTICAL CASSETTE HOLDER	☐ IMAGE INTENSIFIER
☐ TUBE HOUSING ASSEMBLY	☐ SPOT FILM DEVICE
☐ DENTAL TUBE HEAD	☐ OTHER *(Specify)*

5. ASSEMBLER CERTIFICATION

I affirm that all certified components assembled or installed by me, for which this report is being made, were adjusted and tested by me according to the instructions provided by the manufacture(s), were of the type required by the manufacturer(s), were of the type required by the diagnostic x-ray performance standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installed in accordance with provisions of 21 CFR Part 1020. I also affirm that all instruction manuals and other information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser and, within 15 days from the date of assembly, each copy of this report will be distributed as indicated at the bottom of each copy.

a. PRINTED NAME	b. SIGNATURE	c. DATE

6. COMMENTS

FORM FDA 2579 (10/97) PREVIOUS EDITION IS OBSOLETE EF

White Copy - FDA, HFZ-307,2098 Gaither Road, Rockville, MD 20850

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	**CLAIM FOR DAMAGE TO AN ELECTRONIC PRODUCT** *(See Instructions on Reverse)*

I. COMPLETED BY CLAIMANT

NAME AND MAILING ADDRESS *(Include Zip Code)*

I hereby request $ _____ for damage to my _____, make _____, Model Number _____, Serial Number _____, which was damanged during Food and Administration testing on _____, 19_____.

SIGNATURE	DATE

II. COMPLETED BY FOOD AND DRUG INSPECTOR

I affirm that the _____ listed above, with a (repair/replacement) value of $_____, was (damaged/damaged beyond repair) in my presence during an official test under the provisions of Public Law 90-602.

NAME, ORGANIZATION, AND ADDRESS *(Print)*	SIGNATURE
	DATE

III. COMPLETED BY IMMEDIATE SUPERVISOR, EMPLOYEE OR REPRESENTATIVE

I affirm that the above employee or representative was on official government business when this claim for damage arose.

NAME AND TITLE *(Print)*	SIGNATURE	DATE

IV. COMPLETED BY OFFICE OF COMPLIANCE AND SURVEILLANCE, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

COMMON ACCOUNTING NUMBER	CDRH CLAIM NUMBER

COMMENTS:

FORM FDA 2766 (1/93) 53

CONTACTS FOR MANUFACTURERS OF DIAGNOSTIC X-RAY SYSTEM CONTROLS

ACOMA MEDICAL IMAGING INC. ACOM
150 CHADDICK DRIVE
WHEELING, ILLINOIS 60090
PHONE NO.- 708 215-2737

ADVANTECH SYSTEMS ADEH
24 TORRICE DRIVE
P.O. BOX 2700
WOBURN, MA 01888
PHONE NO.- (617) 933-5363

ADVANCED MEDICAL SYSTEMS, INC. ADME
121 NORTH EAGLE STREET
GENEVA, OH 44041
PHONE NO.- (216)466-4671

ADVANCED INSTR DEVELOPMENT INC ADVI
1011 N 25TH AVENUE
MELROSE PARK, ILL 60160
PHONE NO.- (708)343-7777

ADVANCED RESEARCH APPL.CORP. ADVR
425 LAKESIDE DRIVE
SUNNYVALE, CA 94086-4701
PHONE NO.- (408) 733-7780

AFP IMAGING AFPI
250 CLEARBROOK ROAD
ELMSFORD, NY 10523-1315
PHONE NO.- (914)592-6100
(AGENT FOR ORION CORPORATION)
(ALSO SELLS UNDER DENTX LABEL)

AMEDCO HEALTH CARE, INC.
401 SOUTH OUTER SERVICE ROAD AMHR
WRIGHT CITY, MISSOURI 63390
PHONE NO.- 314-745-3173

AMERISYS AMRY
191 MITCHELL COURT
ADDISON, ILLINOIS 60101
PHONE NO.- 708 916-8211

AMERICAN SCIENCE & ENGINEERING
FORT WASHINGTON AMSE
829 MIDDLESEX TURNPIKE
CAMBRIDGE, MA 01821
PHONE NO.- 508-262-8700

BETA MEDICAL PRODUCTS, INC. BEMI
530 SOUTH MAIN ST.BUILDING 17
AKRON, OH 44311
PHONE NO.- (216) 253-7766

BENNETT, SUB. OF TREX MED.COR. BEXR
54 RAILROAD AVENUE
COPIAGUE, NY 11726-2719
PHONE NO.- (516)691-6100

BIODEX MEDICAL SYSTEM INC. BIDX
BROOKHAVEN R&D PLAZA
20 RAMSAY ROAD BOX 702
SHIRLEY, NY 11967-0702
PHONE NO.- (516) 924-9000
ATOMIC CORP. HAS MERGED WITH BIODEX

BIOSTERILE TECHNOLOGY, INC.
2702 C.R. 68 BIOY
AUBURN, INDIANA 46706
PHONE NO.- 219 925-4665

CANON U.S.A. INC CANO
ONE CANON PLAZA
LAKE SUCESS, NY 11042
PHONE NO.- (516)488-1400

CARDIO SYSTEMS INC. CAOS
P.O. BOX 29923
DALLAS, TX 75229
PHONE NO.- 1-800-527-0443

CIAS X-RAY (DELTA THERM) CIAS
398 W. LIBERTY
P.0. BOX 345
WAUCONDA, IL 60084
PHONE NO.- (708)526-2407

CONCORD E & I LTD COIX
1230 CLAUSSEN DRIVE
WOODSTOCK, IL. 60098
PHONE NO.- (815) 338-0208

COMPUTERISED MEDICAL SYSTEMS COMM
3555 WOODHEAD DRIVE
NORTHBROOK, ILLINOIS 60062
PHONE NO.- (312) 564-3311

CONTACTS FOR MANUFACTURERS OF DIAGNOSTIC X-RAY SYSTEM CONTROLS

CONTROL-X INC COXI
2289 WESTBROOKE DRIVE
COLUMBUS, OHIO 43228
PHONE NO.- 614 777-9729

CONTINENTAL X-RAY CORP
CONX
2000 SOUTH 23TH AVENUE
BROADVIEW, IL 60153
(SUBSIDARY OF TREX MED CORP)

CREOS LIMITED CRSO
7388 S. REVERE PARKWAY
SUITES 1003/1004
ENGLEWOOD, COLORADO
PHONE NO.- 303 790 8888

DENAR CORPORATION DECO
901 E. CERRITOS AVENUE
ANAHEIM, CA 92805-6475
TELEPHONE NO.- 714 776-9000

BENNETT, SUB. OF TREX MED.COR. DIAL
445 OAK ST.
COPIAGUE, NY 11726-2719
PHONE NO.- (516)691-6100
(FORMERLY KNOWN AS DIAL-X INSTRUMENTS, INC.)

OEC-DIASONICS, INC. DIAS
384 WRIGHT BROTHERS DRIVE
SALT LAKE CITY, UT 84116
TELEPHONE NO.- (801) 328-9300

DIAMED, INCORPORATED DIDC
23322 S. POINTE E.
LAGUNA HILLS, CA 92653
PHONE NO.- (714)859-6434

DIGIRAY CORP.
2239 OMEGA ROAD, SUITE 3 DIGO
SAN RAMON, CA 94583
PHONE NO.- (415) 838-1510

DOVE MEDICAL SYSTEMS, INC. DOVM
3533 OLD CONEJO RD. SUITE 103
NEWBURY PARK, CA 91320
PHONE NO.- (805)375-8436

DIAGNOSTIC RADIOLOGICAL DEVICE DRAD
60 COIT STREET
IRVINGTON, NEW JERSEY 07111
PHONE NO.- 201 374-2400

DYNARAD CORP.
DYRA
19 JEFRYN BLVD. WEST
DEER PARK, NY 11729
PHONE NO.- 516-242-5550
PORTA RAY, INC. SOLD TO DYNARAD

EAGLE X-RAY COMPANY EAGX
P.O. BOX 60
50 PINE ST.
COPIAGUE, NY 11726
PHONE NO.- 516 691-6100

EDAP TECHNOMED INC. EDAP
179 SIDNEY STREET
CAMBRIDGE, MA 02139
PHONE NO.- 617-441-9212

MARQUETTE MEDICAL SYSTEMS EFOR
E FOR M IMAGING SYSTEM DIV.
625 ALASKA AVE.
TORRANCE, CA 90503
PHONE NO.- 310-320-8334

DU PONT DE NEMOURS & CO. EIDU
R.D. 1, BOX 15
TOWANDA, PA 18848-9784
PHONE NO.- (717) 265-6141

EIGEN EIGE
P.O. BOX 848
NEVADA CITY, CA 95959
PHONE NO.- (916) 265-2020

EIMAC EIMA
1678 S. PIONEER ROAD
SALT LAKE CITY, UTAH 84104
TELEPHONE NO.- (801) 972-5000

EKTRON APPLIED IMAGING EKTA
23 CROSBY DRIVE
BEDFORD, MA 01730
PHONE NO.- (617)275-0475

CONTACTS FOR MANUFACTURERS OF DIAGNOSTIC X-RAY SYSTEM CONTROLS

ELSCINT, INC. ELSC
3550 SALT CREEK RD. SUITE 105
ARLINGTON HEIGHTS, IL 60005
PHONE NO.- 312-577-2266

ELEMA SCHONANDER, INC ELSI
2360 PALMER DRIVE
SCHAUMBURG ILLINNOIS 60173
PHONE NO.- 708 397-5900

INMQ-INTERN MEDICAL SYSTEM INC EUEL
4181 LATHAM STREET
RIVERSIDE, CA 92501
PHONE NO.- (714) 781-2020

EURO-ELECTRONICS, INC. EURE
4181 LATHAM STREET
RIVERSIDE, CA. 92501
PHONE NO.- (714) 781-2020

EUREKA X-RAY TUBE, INC EUXR
600 W. UNIVERSITY DRIVE
ARLINGTON HTS. IL 60004-1818
PHONE NO.- (708) 394-5800

EWA INDUSTRIES, INC. EWAI
P.O. BOX 970161
MIAMI, FL 33197
TELEPHONE NO.- (305) 233-1013

HENRY FAINSZTEIN IMAGING SYS. FAIN
8582 KEEL DRIVE
HUNTINGTON BCH., CA 92646-2105
PHONE NO.- 485-2372

FLUOROSCAN IMAGING SYSTEMS FLSY
650-B ANTHONY TRAIL
NORTHBROOK, ILLINOIS 60062
TELEPHONE NO.- 1-847-564-5400

FUJI MED SYSTEM U.S.A.INC. FUJP
333 LUDLOW STREET
P.O. BOX 120035
STAMFORD, CT 06912
PHONE NO.- 201 353-0300

GENERAL ELECTRIC COMPANY GECO
P.O. BOX 414, W-657
MILWAUKEE, WISCONSIN 53201
TELEPHONE NO.- 414 544-3894 -
CONTACT FOR CGR-GE MEDICAL

GENDEX CORPORATION GEDX
901 WEST OAKTON STREET
DES PLAINES, IL 60018-1884
PHONE NO.- (708)640-4800 FAX 640-6165
(ALSO CALLED GENDEX-DEL / DELL CORP
NOW GENDEX INTERNATIONAL)

FISCHER IMAGING CORPORATION HGFC
12300 NORTH GRANT STREET
DENVER, COLORADO 80241
PHONE NO.- (303)452-6800

HITACHI MEDICAL CORP. HITM
710 BBRIDGEPORT AVE
SHELTON CT 06484
PHONE NO.- (203)926-7058

HOFMANN X-RAY OF AMERICA, INC. HOFM
16540 ASTON AVENUE
IRVINE, CA 92714
TELEPHONE NO.- (714) 250-8090

HOLOGIC, INC. HOLD
590 LINCOLN STREET
WALTHAM, MA 02154
PHONE NO.- (617) 890-8031

IMAGING & X-RAY INT'L, INC. IMXR
TWO COMMERCE DRIVE
AIRPORT PARK
WARWICK, RI 02886
PHONE NO.- (401) 738-9277

INSTRUMENTARIUM IMAGING, INC. INRU
300 WEST EDGERTON AVENUE
MILWAUKEE, WISCONSIN 53207
TELEPHONE NO.- 414 747-1030

CONTACTS FOR MANUFACTURERS OF DIAGNOSTIC X-RAY SYSTEM CONTROLS

INT'L MEDICAL DESIGNS, INC. INCD
303 ELNORA AVE
DELTONA, FLORIDA
32738
PHONE NO.- (407)321-4034

INFIMED, INC. INFC
121 METROPOLITAN DR.
LIVERPOOL, NY 13088
PHONE NO.-

INTERNATIONAL MEDICAL SYSTEMS INMQ
4181 LATHAM STREET
RIVERSIDE, CALIFORNIA 92501
PHONE NO.- 909 781-2020

INMARK CORPORATION INMR
4 BYINGTON PLACE
NORWALK, CT 06850
PHONE NO.- (203)-866-8474

INNERSCAN INC.
INNZ
150 CHADDICK DRIVE
WHEELING, IL 60090
PHONE NO.-

INLAND TUBE CORPORATION INON
COMMERCE SECURITY CENTER
5300 NORTHEAST 13TH WAY
POMPANO BEACH, FL 33064
PHONE NO.- (305) 481-1677

INNOSERV TECHNOLOGIES, INC. INOS
4330 BELTWAY, SUITE 520
ARLINGTON, TX 76018
PHONE NO.-

INT'L MEDICAL ENTERPRISE
INRM
1630 N. MAIN, SUITE 101
WALNUT CREEK, CA 94596
PHONE NO.- (415) 935 7769

INSIGHT SYSTEMS INSN
P.O. BOX 1057
FONTANA, CA 92334
PHONE NO.- (909) 620-7956

VARIAN INTERAY INYI
3235 FORTUNE DR.
NORTH CHARLESTON, SC 29418
PHONE NO.- (803) 767-3005

INST. FOR RAD. IMAGE SCI, INC IRIS
20251 CENTURY BLVD
GERMANTOWN, MD 20874
PHONE NO.- (301) 540-2440

JANNX MEDICAL SYSTEMS, INC. JANX
DIAGNOSTIC IMAGING DIVISION
12166 OLD BIG BEND BOULEVARD
SUITE 300
ST. LOUIS, MISSOURI 63122
PHONE NO.- (314) 822-7799

KANSAS CITY X-RAY CORPORATION KANC
5604 TROOST AVE.
KANSAS CITY, MO 64110
PHONE NO.- (816)444-5700

KAYCOR INTERNATIONAL LTD. KAYC
3611 COMMERCIAL AVENUE
NORTHBROOK, IL 60062
PHONE NO.- (847) 564-4334

KEITHLEY INSTRUMENTS, INC KEIT
28775 AURORA ROAD
CLEVELAND, OH 44139
PHONE NO.- (216) 248-0400

KEVEX CORPORATION KEVX
320 EL PUEBLO
SCOTTS VALLEY, CA 95066
PHONE NO.- (408) 438-5940

KEYSTONE X-RAY, INC. KEYS
3535 ROUTE 66
NEPTUNE, NJ 07753
PHONE NO.- (201) 922-8555

LECTUS INC. LECQ
101 SAGINAW DRIVE
REDWOOD CITY, CA 94063
PHONE NO.- 415 361-1560

CONTACTS FOR MANUFACTURERS OF DIAGNOSTIC X-RAY SYSTEM CONTROLS

LIXI, INC. LIXI
1438 BROOK DRIVE
DOWNERS GROVE, IL. 60515
PHONE NO.- (708)620-4646

LORAD CORP. LORA
(DIVISION OF TREX MEDICAL)
36 APPLE RIDGE ROAD
DANBURY, CT. 06810-710
PHONE NO.- 203-790-5544 ¶

LUNAR CORPORATION
LUNA
313 W. BELTLINE HIGHWAY
MADISON, WI 53713
PHONE NO.- (608) 274-2663

MACHLETT LABORATORIES, INC. MALA
1063 HOPE STREET (NO LONGER IN BUSINESS)
STAMFORD, CT 06907
PHONE NO.- (203) 348-7511

C.L. MCINTOSH MCAI
12300 TWINBROOK PKWY.
SUITE 625
ROCKVILLE, MD 20852
PHONE NO.- (301) 770-9590

MDT DIAGNOSTIC COMPANY MDTC
7371-B SPARTAN BLVD EAST
P.O. BOX 40488
NORTH CHARLESTON, SC 29423
TELEPHONE NO.- (803) 552-8652

MEDICOR U.S.A. LIMITED MECO
2289 WESTBROOKE DRIVE
COLUMBUS, OHIO 43228
TELEPHONE NO.- 800-777-XRAY

MEDICAL MARKETING INT'NATL MEMI
12748 EAST MILBURNE AVENUE
BATON ROUGE, LA
PHONE NO.-

MEICOR, INC. MEOO
322 WARREN AVE.
FREMONT, CA 94539
PHONE NO.- (415) 656-0882

MEDSTONE INTERNATIONAL INC. MEOT
100 COLUMBIA SUITE 100
ALISO VIEJO, CA 92656
TELEPHONE NO.- (714) 448-7700

MEDIREX, INC. MERX
49 WALNUT PARK, BLDG. 4
WELLESLEY HILLS, MA 02181
PHONE NO.- (617) 235-8101

MEADRAD, INC. METP
RT 910 MEDRAD DR P.O BOX 780
INDIANOLA, PA 15051
PHONE NO.- 412 967-9700 EXT 3285

GENDEX MIDWEST DENTAL PROD MIDE
901 W. OAKTON STREET
DES PLAINES, IL 60018
PHONE NO.- (708)640-4800

MICRO FOCUS IMAGING MIFC
225 LARKIN DRIVE, UNIT 1
WHEELING, IL 60090
PHONE NO.-

MINXRAY, INC. MINX
3611 COMMERCIAL AVENUE
NORTHBROOK, IL 60062-1822
PHONE NO.- (847) 564-0323

MRX-RAY TUBE CORPORATION MRXR
320 WESTWAY PLACE, SUITE 520
ARLINGTON, TX 76018
PHONE NO.-

MTD, INC. MTDI
365 AMITY ROAD
ANDOVER, NJ 07821
PHONE NO.- 201 347-5238

NORTH AMERICAN IMAGING, INC. NOAI
924 VIA ALONDRA
CAMARILLO, CA 93012
PHONE NO.- (805) 383-2200

NORLAND MEDICAL SYSTEMS, INC. NOLC
W6340 HACKBARTH RD.
FORT ATKINSON, WI 53538
PHONE NO.- (920) 563-9504

CONTACTS FOR MANUFACTURERS OF DIAGNOSTIC X-RAY SYSTEM CONTROLS

NUCLETRON CORPORATION NUCT
7080 COLUMBIA GATEWAY DRIVE
COLUMBIA, MD 21046-2133
PHONE NO.- (410) 312-4100

OEC MEDICAL SYSTEMS, INC. OECD
384 WRIGHT BROTHERS DRIVE
SALT LAKE CITY, UT 84116
PHONE NO.- (801) 328-9300
(ORIGINALLY OEC-DIASONICS (MFR CODE DIAS))

OLYMPIC CONTROLS CORP. OLCO
1080 E. CHICAGO ST.
ELGIN, IL 60120
PHONE NO.-

OLDELFT CORP. OF AMERICA OLDE
9108 GUILFORD ROAD
COLUMBIA, MD 21046
PHONE NO.- (410) 498-4303

OLYMPIC MEDICAL CORP. OLME
5900 FIRST AVE SOUTH
SEATTLE, WA 98108
PHONE NO.- (206)767-3500

ORION CORP (SOREDEX MED SYSTS) ORIC
200 BEACH AIRPORT ROAD
RT. 21, BOX 200
CONROE, TEXAS 77301
TELEPHONE NO.- (409)760-3198
(SEE ALSO SORE- ORION CORPORATION SOREDEX)

PAUSCH CORPORATION PAUS
808 SHREWSBURY AVENUE
TINTON FALLS, NJ 07724-3002
PHONE NO.- (908)747-6110

PERKINS MANUFACTURING CO. PERY
1510 NORTH WASHINGTON AVE.
DALLAS, TX 75204
PHONE NO.- (214) 828-4545

PHILIPS MEDICAL SYSTEMS PHMS
P.O. BOX 860
710 BRIDGEPORT AVE.
SHELTON, CT 06484-0917
PHONE NO.- (203) 926-7674

PICKER INTERNATIONAL PICO
595 MINER ROAD
CLEVELAND OH 44143
PHONE NO.- (216)473-3000

PLANMED, INC. PLME
362 BALM COURT
WOOD DALE, IL 60191
PHONE NO.- (630) 595-9317

PORTA RAY, INC. PORT
19 JEFRYN BLVD. WEST
DEER PARK, N. Y. 11729
PHONE NO.- (516) 242-0022
(SEE DYNARAD - DYRA AFTER 04/91)

PRECISE OPTICS
239 SOUTH FEHR WAY PREO
BAYSHORE, NY 11706
PHONE NO.- (7_[D516) 242-6600

PROFESSIONAL MEDICAL PRODUCTS PRMP
525 N. EMERALD ROAD
GREENWOOD, SC 29646
PHONE NO.- (803) 223-4281

PROGENY, INC. PRYN
600 W. UNIVERSITY DR.
ARLINGTON HEIGHTS, IL 60004
PHONE NO.- (847) 342-0700
BLDS FORMERLY MADE BY EUREKA X-RAY COMPANY

PURITAN-BENNETT CORP. PURB
9401 INDIAN CREEK PARKWAY
P.O. BOX 25905
OVERLAND PARK, KS 66225
PHONE NO.- (816)421-2122

RAYTHEON MEDICAL SYSTEMS RAYM
2301 WINDSOR COURT
ADDISON, IL 60101
PHONE NO.- 708 627-0900
(NOW RMS FISCHER IMAGING)

CONTACTS FOR MANUFACTURERS OF DIAGNOSTIC X-RAY SYSTEM CONTROLS

ROEHREN LOADING STATION ROEH
16610 ASTON STREET
IRVINE, CA 92714
PHONE NO.- (714)641-1304

R SQUARED SCAN SYSTEMS RSQU
1611-B POMONA ROAD
CORONA, CA. 91720
TELEPHONE NO.- (714) 736-3700

RWS ENGINEERING CO. RWSE
10535 S.W. 185 TERRACE
MIAMI, FL 33157
PHONE NO.- (305)233-7787

SCHICK TECH., INC. SCIH
31-00 47TH AVE.
LONG ISLAND CITY, NY 11101
PHONE NO.- (718) 937-5765

SCIENCE & TECHNOLOGY, INC. SCTE
2121 RICHWOOD DRIVE
GARLAND, TEXAS 75042
PHONE NO.- (214) 272-8896

SEIKO INSTRUMENTS U.S.A. SEIK
2990 WEST LOMITA BLVD.
TORRANCE, CA 90505
PHONE NO.- 800 234-0422

SIEMENS MEDICAL SYSTEMS, INC. SIEC
186 WOOD AVENUE SOUTH
ISELIN, NEW JERSEY 08830
PHONE NO.- (201) 321-4500

SITCO INCORPORATED
3456 N. RIDGE AVENUE SITO
ARLINGTON HEIGHTS, IL 60004
PHONE NO.-

SPECTRUM X-RAY CORPORATION SPEX
P.O. BOX 155, RYAN AVE
WESTVILLE, NEW JERSEY 08093
PHONE NO.- (609)845-0944

S. & S. X-RAY PRODUCTS INC. SSXR
1101 LINWOOD STREET
BROOKLYN, NEW YORK 11208
PHONE NO.- 800-221-6634

NEW PRODUCT DEVELOPMENT STRY
STRYKER CORPORATION
420 ALCOTT STREET
KALAMAZOO, MI 49001
PHONE NO.-

SUMMIT INDUSTRIES INC. SUMD
2901 W LAWRENCE AVE
CHICAGO, IL 60625
PHONE NO.- 312 588-2444

SWISSRAY EMPOWER, INC. SWIE
49 HERB HILL ROAD
GLEN COVE, NY 11542
PHONE NO.- 818-969-7779

SYNTEX DENTAL PRODUCTS, INC SYNT
P O BOX 896
VALLEY FORGE, PA. 19482
PHONE NO.- (215)666-9050

TECNOMED USA TECN
235 SOUTH FEHR WAY
BAYSHORE, NY. 11706
TELEPHONE NO.- (516) 586-1991

TEMPO TECHNOLOGY, INC. TEPO
2090 W. DOWELL ROAD
COLUMBIA CITY, IN 46725
PHONE NO.- (219) 244-4613

EDAP TECHNOMED INC. TEYS
179 SIDNEY STREET
CAMBRIDGE, MA 02139
PHONE NO.- (617) 441-9212

TINGLE X-RAY PRODUCTS, INC. TING
10629 TXR ROAD
VANCE, AL 35490
PHONE NO.- (205) 556-3803

CONTACTS FOR MANUFACTURERS OF DIAGNOSTIC X-RAY SYSTEM CONTROLS

TOKO AMERICA INC.
1250 FEEHANVILLE DR. TOKA
MT. PROSPECT, IL 60056
PHONE NO.- 708 297-0070

TOSHIBA MEDICAL SYSTEMS TOSE
2441 MICHELLE DRIVE
TUSTIN, CALIFORNIA 92680
PHONE NO.- (714) 730-5000

TOSHIBA AMERICA ELECTRONIC TOSA
ONE PARKWAY NORTH, SUITE 500
DEERFIELD, IL 60015-2547
PHONE NO.- (847) 945-1500

TREX MEDICAL CORP LORAD DIV TREX
36 APPLE RIDGE ROAD
DANBURY, CT 06810
PHONE NO.- 203-790-1188
(SELLS UNDER LABELS LORA, BEXR, DIAX,CONX)

TUBEMASTER INC. TUBE
525 W. ROCK ISLAND RD.
GRAND PRARIE, TX 75050
PHONE NO.- 214-986-7144

UNIVERSAL/ALLIED IMAGING, INC. UNIV
4014 WEST GRAND AVENUE
CHICAGO, ILLINOIS 60651
PHONE NO.- (312) 276-4400

VARIAN ASSOCIATES, INC. VARA
3045 HANOVER STREET
PALO ALTO, CA 94304-1129
PHONE NO.- (415) 493-4000

VARIAN INTERAY VARA
3235 FORTUNE DRIVE
NORTH CHARLESTON SC 29418
PHONE NO.- 803-767-3005

VIDEO-OPTICS INC. VIOO
100 ALBRIGHT WAY
LOS GATOS, CA 95030
PHONE NO.- (408) 378-8460

VISISCAN VISI
16540 ASTON ST.
IRVINE, CA 92714
PHONE NO.- (714) 261-8503

V.J. TECHNOLOGIES
89 CARLOUGH ROAD VJTE
BOHEMIA, N.Y. 11716
PHONE NO.- 516 589-8992

WUESTEC MEDICAL INC. WUES
421 HOLCOMBE AVE.
MOBILE AL 36606
PHONE NO.-

X-CEL X-RAY CORPORATION XCEL
4220 WALLER DRIVE
CRYSTAL LAKE, IL 60012
TELEPHONE NO.- (815) 455-2470

XI TECH, INC. XITE
85-159 AIR EXCHANGE BLDG
WINDSOR LOCKS, CT 06096
PHONE NO.- 203 627-7500

X-RAY TECHNOLOGIES, INC. XRAZ
6420 N. HAMLIN AVENUE
LINCOLNWOOD, IL 60645
PHONE NO.- 847-675-9736

XRE CORPORATION XRCO
300 FOSTER STREET
P.O. BOX 1154
LITTLETON, MA 01460
PHONE NO.- 508-486-9681

X-RAY MARKETING ASSOCIATES,INC XRMI
1205 LAKEVIEW COURT
ROMEOVILLE, IL 60441
PHONE NO.- (708)378-1992

NOTE: CONTACT THE HOME DISTRICT OEI OR THE CENTER (HFZ-300) WHEN MANUFACTURER ADDRESS PROBLEMS ARISE.

(NOTIFICATION LETTER)
(TO ASSEMBLERS FOR CORRECTION OR COMPLETION OF SUBMITTED FDA 2579's)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (Addressee) :

On (date) your firm was inspected/contacted by (investigator) from our (Location) District office. At that time, he (she or they) explained to you (or name & title of agent) your firm's responsibility as an assembler to submit complete and accurate Reports of Assembly of a Diagnostic X-ray System, Form FDA 2579, for each diagnostic x-ray component (system) installed by your firm.

Accurate and complete Reports of Assembly of a Diagnostic X-ray System, Form FDA 2579, are required to be submitted to FDA within 15 days following the completion of assembly pursuant to 2l CFR l020.30 (copy enclosed).

We are requesting that you provide us with a corrected Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, within 30 working days of the receipt of this letter for (FDA 2579 number), which is for equipment assembled at (location). A copy of the report you previously submitted is enclosed.

Along with a corrected FDA 2579, you should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. Your response should be sent to (name), Compliance Officer, Food and Drug Administration, (street address), (city), (state & zip code). If you have any questions, (name) can be contacted at (telephone #).

Sincerely,

(NOTIFICATION LETTER)
(TO ASSEMBLERS FOR STANDARDS VIOLATIONS FOUND DURING REVIEW OF FDA 2579's OR RECORDS REVIEW AT THE ASSEMBLER)

CERTIFIED MAIL RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (addressee) :

During an inspection of your firm located in (address) , conducted on (date) , our Investigator(s) determined that your firm is an assembler of diagnostic x-ray equipment. At that time, he (she or they) specifically discussed your assembly of a general purpose radiographic unit at (location) and explained to you that your installation of a beam limiting device which does not provide variable beam limitation on such a unit was in violation of 21 CFR 1020.31(d)(1).

At that time you agreed to replace the beam limiting device with the type called for by the standard, i.e., variable x-ray field limitation, and submit a corrected Report of Assembly of a Diagnostic X-ray System, Form FDA 2579 to the Food and Drug Administration, the State Radiation Control Program, and the purchaser by (date) . Please use the enclosed forms for this purpose. We have enclosed an envelope for your use in returning the original (white) copy directly to this office.

Subsequent to (date agreed upon) , a representative of the Food and Drug Administration may investigate your assembly at (location) to verify your correction.

Failure to correct a defect or noncompliance or failure to file a Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, is a violation of the Federal Food, Drug, and Cosmetic Act (the Act), section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of l968).

Accurate and complete Reports of Assembly of a Diagnostic X-ray System, Form FDA 2579, are required to be submitted to FDA within 15 days following the completion of assembly pursuant to 2l CFR l020.30.

Along with a revised FDA 2579, you should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation(s), including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to (name) , Compliance Officer, Food and Drug Administration,

(street address), (city), (state & zip code). If you have any questions, (name) can be contacted at (telephone #).

Sincerely,

Enclosures

(NOTIFICATION LETTER)
(TO ASSEMBLERS -FAILURE TO FILE FDA 2579 REPORTS OF ASSEMBLY)

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (addressee) :

During an inspection of your firm located in (address), conducted on (date), our Investigator(s) determined that your firm is an assembler of diagnostic x-ray equipment. At that time, he (she or they) explained to you (or to your agent) your responsibility to file a Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, for each certified diagnostic x-ray component (system) you assemble (see attached copy of applicable regulations). We have identified the following facility(s) for which your assembly was not reported to FDA in accordance with 21 CFR 1020.30:

l. (name and location)

2. (name and location)

etc.

Accurate and complete Reports of Assembly of a Diagnostic X-ray System, Form FDA 2579, are required to be submitted to FDA, the appropriate State Radiation Control Program, and the purchaser within 15 days following the completion of assembly pursuant to 2l CFR l020.30.

Failure to file a Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, is a violation of the Federal Food, Drug, and Cosmetic Act (the Act), section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of l968).

Along with a FDA 2579 for each of the above listed installations, you should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. Your response should be sent to (name), Compliance Officer, Food and Drug Administration, (street address), (city), (state & zip code).
If you have any questions, (name) can be contacted at (telephone #).

Sincerely yours,

Enclosures

(NOTIFICATION LETTER)
(NOTIFICATION OF DEFECT/NONCOMPLIANCE AS THE RESULT OF FIELD TESTING)

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear _____:

On (date), FDA performed a field test of a certified diagnostic x-ray system which your firm assembled on (date), according to Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, (number). We tested this system to determine its compliance with portions of the Performance Standard for Diagnostic X-ray Equipment (Title 21, Code of Federal Regulations (CFR), sections 1020.30-32). Diagnostic x-ray equipment are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). This field test, Test ID # ____, was performed at:

Name of Facility
Address
City, State, Zip Code
X-ray Control Manufacturer
X-ray Control Model # _____, Serial #
Room Number

WHEN YOU HAVE A CLASS A VIOLATION INSERT THE FOLLOWING:

This letter confirms our telephone notification of (date) to Mr./Ms. (name) of your firm regarding a serious noncompliance with the performance standard and our request that you immediately correct this violation.

(Note: When there is a Class A violation, the letter will be titled "WARNING LETTER" and time frames will be 15 working days instead of 30 working days. There will be appropriate warning letter tracking and follow up. The signature block should be for the District Director for WARNING letters).

Example of a Class A Violation

We measured the entrance exposure rate of the fluoroscopic system to be 27 Roentgens per minute at the point where the center of the useful beam enters the patient. This condition is a serious radiation health hazard and warrants your immediate attention.

21 CFR 1020.32(d)(1) limits the entrance exposure rate to 10 Roentgens per minute for systems with automatic exposure rate control.

WHEN YOU DECLARE A CLASS B VIOLATION, INSERT THE FOLLOWING:

Our analysis of the field test data indicates that the system does not comply with the following items of the performance standard:

Example of a Class B Violation

We measured the illuminance of the light localizer to be 126 Lux at 100 centimeters. 21 CFR 1020.31(d)(2)(ii) requires that the average illuminance be 160 Lux or more at 100 centimeters or the maximum SID, whichever is less.

WHEN YOU DECLARE A DEFECT, INSERT THE FOLLOWING:

While conducting our field test, we determined that the system was defective in the following manner:

Example of a Defect

The x-ray system would initiate x-ray exposure without activation of the exposure button.

WHEN YOU HAVE A CLASS C VIOLATION AND YOU ARE DECLARING CLASS A AND/OR B VIOLATIONS OR A DEFECT, ADD THE FOLLOWING:

In addition to the above problems, we consider the compliance status on the following item(s) to be suspect. Please verify the compliance status of this item (these items) when you correct the previously cited problems.

Example of a Class C Violation

We measured the difference between the x-ray field size and the image receptor size, in the plane of the undertable image receptor to be 3.8 percent of the SID for the across table dimension. The cassette size was 8" x 10" and SID was 40 inches. 21 CFR 1020.31(g)(1)(i) requires that the x-ray field and image receptor length or width difference in the plane of the image receptor be no greater than 3 percent of the SID.

We request that you, as the responsible assembler, immediately investigate the deviation(s) from the performance standard cited above in accordance with 21 CFR 1003 and 1004 as follows:

1. If you determine that the deviations and/or defect(s) is (are) caused by improper assembly or installation, you must correct them and/or the defect(s) at no charge to the user by either repairing the system, replacing it, or refunding the cost.

2. If you determine that the deviations and/or defect(s) is (are) caused by the factory-based manufacturer, you must notify him of the noncompliance(s) and/or defect(s) and send documentation of such notification to this office.

3. If you can establish that the system is compliant, that the alleged deviation or defect does not exist or does not relate to the safety of the product, or is directly attributable to user abuse or lack of maintenance, you may submit such evidence in accordance with 21 CFR 1003.30 within 30 working days of receipt of this letter.

You must report the results of your investigation and follow-up actions to this office within 30 working days of receipt of this letter. Your response should include the date that the corrective action was completed and copies of service records and/or other supportive documents. If you do not respond within 30 working days, the FDA may consider you to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), sections 538(a)(2) and 538(a)(4) of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of l968).

Please note that improper installation, including failure to follow installation instructions which cause the system to be noncompliant with the Performance Standard may cause the system to be adulterated. Under 501(c) of the Act the system would not be of a quality represented by the labeling (including the certification statement).

Failure to promptly correct this violation(s) can result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include seizure and/or injunction and/or the imposition of civil penalties as provided for in section 539 of the Act. Persons violating section 538 of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000.

You should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation(s), including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to (name), Compliance Officer, Food and Drug Administration, (street address), (City, State & zip code).

If you have any questions, (name) can be contacted at (telephone #).

Sincerely yours,

X-RAY FIELD TEST NON-COMPLIANCES THAT ARE UNRESOLVED IN ATLANTA HOME DISTRICT

TEST ID	TEST DATE	ACCOMP DISTRICT	FACILITY/ZIP ASSEMBLER/ZIP	NONCOMPLIANCES
AR56175R	19961009	LOS	MOBILE LITHOTRIPTERS/92630 DORNIER MEDICAL SYSTEMS INC./30144	Q07 Q08 Q71
AR54497A	19961018	ATL	NORTHSIDE HOSPITALL/30342 PICKER INTERNATIONAL/30071	9
UF55410B	19961029	NOL	VICKSBURG MEDICAL CENTER/39180 GENERAL ELECTRIC COMPANY/30071	10
UF55415B	19970123	NOL	MONFORT JONES MEMORIAL HOSPITAL/39090 PICKER INTERNATIONAL/30071	8 9
AR64877A	19970127	ATL	PROMINA PRIMARY CARE CENTER/30060 RAMSEY ENTERPRISES INC./30188	Q54
AR56372A	19970130	ATL	THE PAPP CLINIC/30265 X-RAY OF GEORGIA, INC./30071	2
UF56357B	19970214	ATL	KAISER PERMANENTE, SPMO/28210 GENERAL ELECTRIC COMPANY/30071	16
AR37356A	19970305	NOL	HUEY P. LONG REGIONAL MED CNT/71360 GENERAL ELECTRIC COMPANY/30071	3
AR55416	19970312	NOL	BAPTIST MEMORIAL HOSPITAL/38671 UNKNOWN (CFN: 1043749)	3 5
AR57378A	19970318	ATL	CANDLER HOSPITAL/31405 GENERAL ELECTRIC COMPANY/30071	3
AR58973A	19970319	ATL	CANDLER HOSPITAL/31405 GENERAL ELECTRIC COMPANY/30071	3
AR58972A	19970320	ATL	MEDICAL CENTER LLP/31021 X-RAY OF GEORGIA, INC./30071	9
AR50490A	19970509	NSV	ST. CLAIRE REGIONAL HOSPITAL/35125 UNKNOWN (CFN: 1056430)	Q54 Q69 Q70
AR57884A	19970515	ORL	MORTON PLANT MEASE HOSPITAL/34698 GENERAL ELECTRIC COMPANY/30071	Q71
UF57943B	19970611	ORL	MIAMI CHILDRENS HOSPITAL/33155 GENERAL ELECTRIC COMPANY/30071	12
AR43600A	19970616	NSV	QUANTUM IMAGING/37203 GENERAL ELECTRIC COMPANY/30071	9 33 35
UF64654C	19970909	ORL	CEDARS MEDICAL CENTER/33136 GENERAL ELECTRIC COMPANY/30071	10
AR64057A	19971030	NOL	FOREST GENERAL HOSPITAL/30401 GENERAL ELECTRIC COMPANY/30071	35
AR57336A	19971112	ATL	OCONEE MEMORIAL HOSPITAL/29679 PHILIPS MEDICAL SYSTEMS, INC./28217	29 31
AR57337A	19971112	ATL	OCONEE MEMORIAL HOSPITAL/29672 PHILIPS MEDICAL SYSTEMS, INC./28217	17 19 21

TOTAL FIELD TEST RECORDS FOR ATLANTA HOME DISTRICT IS: 21

(NOTIFICATION LETTER) (USER)
(NOTIFICATION TO USER/NONCOMPLIANCE AS THE RESULT OF FIELD TESTING)

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (addressee) :

On (date) , a field test was performed on the (name of mfr.) diagnostic x-ray system, control model number _____, located in room ___ of your facility. We tested this system to determine its compliance with portions of the Performance Standard for Diagnostic X-ray Equipment (Title 21, Code of Federal Regulations (CFR), sections 1020.30-32).

Analysis of the data obtained from the field test shows the system fails to comply with the following requirements of the Federal performance standard for diagnostic x-ray systems:

(Describe Each Item of Noncompliance)

Our investigation indicates that neither the manufacturer nor the assembler is likely to be responsible for these noncompliances under the regulations. The use of a noncompliant x-ray system may result in unnecessary radiation exposure to the patient or operator. Therefore, we encourage you to arrange for correction of the noncompliance.

(If Class A Conditions are Involved, Substitute the Following)

Our investigation indicates that neither the manufacturer nor the assembler is likely to be responsible for the noncompliances under the regulations. These problems may pose a serious health hazard to the patient or operator. We strongly encourage you to discontinue use of the system and arrange for its repair immediately.

You are hereby requested to notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted noncompliance. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to (name) , Compliance Officer, Food and Drug Administration, (street address) , (city) , (state & zip code). If you have any questions, (name) can be contacted at (telephone #) .

Sincerely yours,

Note: Indicate at the bottom of the original letter that the state radiation control program has received a copy of this letter.

RESPONSIBILITY FOR DEFECTS AND NONCOMPLIANCES

The Diagnostic X-ray Performance Standard specifies certain limits of responsibility for manufacturers and assemblers of x-ray equipment. Assemblers are responsible only for noncompliances that are "attributed solely to improper assembly or installation..." caused by improperly following the instructions provided by the manufacturer. Manufacturers are responsible for noncompliances caused by improper assembly only if adequate instructions were not provided to the assembler (1020.30(c)). The performance standard does not specifically address the limits of responsibility regarding equipment age or user responsibility.

Manufacturers are required by the performance standard to provide purchasers with a schedule of maintenance necessary to keep the x-ray equipment in compliance with the performance standard. The regulations require manufacturers to provide a maintenance schedule because it is unreasonable to expect x-ray equipment to meet certain performance requirements if proper maintenance is not performed. After the first maintenance is performed or after the time it should have been performed, the assembler may no longer be responsible for requirements affected by proper adherence to the maintenance schedule. Some assemblers of older certified equipment will correct the noncompliance and bill the owner rather than attempting to refute responsibility for the noncompliance. This practice frequently upsets the x-ray system owner since he believes this work should have been performed free of charge.

Evidence that would exempt manufacturers/assemblers from responsibility includes:

1. Failure by the user to follow the manufacturer's prescribed maintenance schedule for those items requiring periodic adjustment.

2. Photographs or other documentation (written description) of physical damage to the x-ray system which was due to abuse.

The manufacturer/assembler may be held responsible if the user has failed to follow the maintenance schedule but the facility has documented continued compliance problems with the system beginning in the warranty period.

Items that may require periodic adjustment under a manufacturer's maintenance schedule include:

a) linearity
b) x-ray field/light field alignment
c) PBL sizing
d) illuminance
e) entrance exposure rate
f) fluoroscopic alignment
g) spot film alignment

h) indication of technique factors
i) signal and warning lights

Some items require adjustment on a time basis while others require adjustment at time of a tube reloading or bulb change in the collimator lamp. The individual maintenance schedule must be checked to determine the applicable situation and time interval.

LIST OF QUALIFIED X-RAY AUDITORS

		PHONE NUMBER/FAX NUMBER
New England District	Michael J. Leal	508-793-0421
New York District	Murray L. Kurzman	516-921-2035
		516-921-3025
Baltimore District	Elizabeth Laudig	301-962-3591
		410-962-2307
Cincinnati District	Terry R. Bolen*	513-684-3501
		513-684-2905
New Jersey District	Tonietta K. Williams	201-645-6233
		201-645-3848
Philadelphia District	Rita Larocca	251-362-0740
	Robert E. Davis	412-644-3394
		412-644-5496
Atlanta District	Stephanie Harrell	404-347-3218
		404-347-4349
Florida District	Janneth Caycedo*	813-228-2671
		813-228-2483
New Orleans District	Karen Smallwood	615-781-5380
	Abraham Maekele	901-544-0345x20
		615-781-5391
New Orleans District	Francis Guidry*	504-589-6344
		504-589-6360
San Juan District	Jorge Martinez*	
Chicago District	Dennis E. Swartz*	313-226-6260
Detroit District	Dennis E. Swartz	313-226-6260
	Leonard Pesetsky	313-226-6260
		313-226-3717
Minneapolis District	Thomas W. Garvin	414-771-7167x12
		414-771-7512
Dallas District	John D. Mays	214-655-8100x125
	Deborah McGee	214-655-8100x138
	Scotty L. Hargrave	214-655-8100x139
	Angela T. Moak	214-655-8100x135
		214-655-8130
Kansas City District	Reggie Cope	913-752-2403
St. Louis District	Reggie Cope*	913-752-2403
		913-752-2413
Denver District	Robert G. Antonsen	303-236-3025
		303-236-3551
Los Angeles District	Ron Alexander	213-252-7877x31
		213-251-7466
San Francisco District	Minh Phan	415-556-4727
		415-556-6499
Seattle District	John Hall	425-483-4932
		206-553-7020

*Providing auditor functions for district

WARNING LETTER
(SAMPLE DISTRICT ORDERED ASSEMBLER RECALL LETTER TO
X-RAY ASSEMBLERS)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (Addressee) :

Field compliance testing of fully certified diagnostic x-ray systems assembled by (firm name) since (date) has shown that (number, i.e.: 43) percent of the x-ray systems tested failed to comply with the Performance Standard for Diagnostic X-ray Systems and Their Major Components (Performance Standard). Diagnostic x-ray equipment are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The Food and Drug Administration (FDA) has issued (number, i.e.: 12) letters to you addressing your firm's noncompliant assemblies, yet you continue to install diagnostic x-ray systems which fail to comply with the Performance Standard. Based on this high rate of noncompliance with the Performance Standard and your inability to provide assurance that x-ray systems which you assemble will comply with the Performance Standard, the FDA has determined that you fail to comply with Title 21, Code of Federal Regulations (21 CFR), section 1020.30(d). The FDA, hereby declares your assemblies since (date) as noncompliant. As noted below you are hereby required to provide user notification and corrective action plan (CAP) for the recall of your assemblies.

You are advised that it is a prohibited act under the Federal Food, Drug, and Cosmetic Act, section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of l968), to fail to correct electronic products that do not comply with an applicable standard, or that have a defect which relates to the safe use of such products. Additionally, under the Act, it is a prohibited act to adulterate a medical device after receipt in interstate commerce. Your installations are in violation of 21 U.S.C. 351(c) because they fail to have the quality that they purport or are represented to possess in that they do not comply with the Performance Standard for Diagnostic X-ray Systems and Their Major Components, 21 CFR 1020.30.

You must respond in writing within 15 working days of receipt of this letter and provide the number of x-ray assemblies you have completed since (date). In responding, you have the following options:

A. Refutation - You may submit your views and evidence to establish that the alleged noncompliances do not exist.

NOTE: Should your refutation not be accepted, you may request a Regulatory Hearing to state your views in accordance with 21 CFR 1003.11(a)(3).

B. Exemption Request - You may request an exemption from user notification and from the obligation to correct the violative assemblies. Your request must include the grounds upon which you base the exemption request (see 21 CFR 1003.30 and 1003.31).

C. Purchaser Notification and Corrective Action - If you neither refute the noncompliances nor request an exemption, you must; (1) notify purchasers of the violative products as specified in 21 CFR 1003.10(b), and (2) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

1. Notification Letters - Requirements for preparing notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter to be sent to purchasers should also be sent to this office for review before it is sent to purchasers.

2. Corrective Action Plan - Requirements for preparing a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4. Note: the cost of any service or correction of violations by FDA directive is not to be passed on to the owner or user.

If you require additional time to prepare your refutation, notification, CAP, or evidence to support an exemption request, you must submit within 15 working days of the receipt of this letter a written request to this office which outlines the reasons for any delays and a reasonable target date for submission of your response. If your response is not received within 15 working days, the FDA may consider you to be in violation of section 538(a)(2) of the Act for failure to submit required reports.

Please be advised that if your refutation or exemption request is not accepted by the FDA, you must submit a CAP for all certified diagnostic x-ray systems you have assembled since (date). An acceptable CAP submission must include:

1. An agreement to test all assemblies of certified components installed since (date), to ensure that all assemblies comply fully with the Performance Standard.

2. A statement of the testing to be performed, and a copy of the test method.

3. An agreement to correct any items of noncompliance detected by the above testing, at no cost to the user. If you can document that the noncompliance is directly attributed to user abuse or attributable to servicing by another party, you may submit this evidence in lieu of correcting the noncompliance.

4. A listing of all equipment to be used in the testing and calibration of diagnostic x-ray systems.

5. An agreement that all equipment that will be used in testing and calibration will be within current calibration.

6. The number of certified systems assembled since (date).

7. A timetable for the correction of all affected systems.

8. An agreement to submit copies of all test data for FDA review.

9. A copy of the notification letter to be sent to affected purchasers or a draft of said letter.

10. Provisions to ensure that all future assemblies of certified diagnostic x-ray systems comply with all aspects of the Performance Standard.

Failure to promptly correct this violation(s) can result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include seizure and/or injunction and/or the imposition of civil penalties as provided for in section 539 of the Act. Persons violating section 538 of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation(s), including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to (Name), Compliance Officer, Food and Drug Administration, (street address), (City, State & zip code). If you have any questions, (name) can be contacted at (telephone #).

Sincerely yours,

District Director

Enclosures

(GUIDANCE FOR EVALUATING AN ASSEMBLER RESPONSE TO A DISTRICT ORDERED ASSEMBLER RECALL)

The Federal Food, Drug, and Cosmetic Act (the Act), section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of l968) affords manufacturers the opportunity to respond to a declaration of defect or noncompliance in one of three ways:

1. Submit evidence to refute the alleged defect or noncompliance.

2. Submit an exemption request.

3. Submit a corrective action plan (CAP).

Generally, noncompliance declarations are prepared in the expectation that the manufacturer will willingly submit a CAP. In reality, some manufacturers appear to have in place a strategy of first attempting to refute the cited noncompliance, then seeking an exemption, and if not successful, submitting a CAP. While such strategy may seem like stonewalling or foot dragging by the manufacturer, this is perfectly legal under the Act.

Evaluating Refutations

If an assembler can demonstrate that more than one individual noncompliant system was not attributable to improper assembly or calibration, he may have a valid refutation for the declaration of noncompliance. The statistics involved in identifying assemblers for coverage in this program are such that a shift of one or two violations greatly affects the decision to pursue a District Ordered Assembler Recall (DOAR). Because of this, we do not include any field tests which are reported to be of manufacturer origin, or are reported as being in dispute.

The refutation must, of course, have a sound basis. The assembler should submit copies of test data and the test method to demonstrate the system fully complied with the Performance Standard at the time of assembly. Unless such evidence is presented, there is no valid basis for the assembler certification of the respective system.

If you would like assistance in evaluating a refutation, please contact the Diagnostic Devices Branch (HFZ-322) at (301) 594-4591.

Exemption Requests

Exemption requests are permitted by FDA regulations, 21 CFR 1003.30. The regulations require the manufacturer to submit his exemption request in writing, within 15 working days of receiving a declaration of defect or noncompliance. In the case where refutation has been denied, the exemption request must be submitted within 15 working days of receiving written denial of the refutation.

Exemption requests may be granted only if the manufacturer submits evidence to demonstrate the failure to comply with the Performance Standard does not create a significant risk of injury, including genetic injury, to any person. Since the capability to evaluate such submission does not exist in most FDA District offices, all exemption requests should be forwarded to the Diagnostic Devices Branch (HFZ-322) for evaluation. The Diagnostic Devices Branch will provide the district with their evaluation and a determination as to the acceptability of the exemption request.

Please note that a manufacturer who has his exemption request denied may contest the denial in a hearing by the Secretary. It is essential therefore, that all exemption requests be submitted to HFZ-322 for proper evaluation.

If an exemption is granted, no further action is required. Since granting an exemption implies no significant hazard to the user, the violative systems cited may not be used for future legal action (civil penalty or injunction) for the same specific violation.

Please note that the Center does not expect to approve many exemption requests, due to the implied health hazard presented by violative field test results.

When the Center's evaluation of the exemption request is received in the district, it will contain either a draft denial letter, or draft approval letter. If the exemption request is denied, the manufacturer is required to submit a CAP within 15 working days of receiving the denial letter. The return receipt should be maintained as evidence of receipt by the manufacturer.

Corrective Action Plan

Corrective action plans (CAPs) must include one of the following options:

1. Repair the noncompliant products.
2. Refund the purchase price of noncompliant product.
3. Replace the noncompliant products with compliant products.

Of the three options, most manufacturers elect to repair the noncompliant components. Since the other two options do not require explanation, only the repair option will be discussed further.

The underlying philosophy of declaring as noncompliant all diagnostic x-ray systems installed over certain time period presupposes that combined FDA/State testing has not tested all systems installed by a particular assembler. This implies that there exist other assemblies (not tested by FDA or the State) of diagnostic x-ray equipment which also fail to comply. The purpose of the noncompliance declaration is to obtain a CAP which will require the testing (and correction) of previously untested system.

An acceptable CAP will contain the following elements:

1. The assembler's proposed method of re-testing all assemblies of certified components installed within specified time period. (CDRH will help the district with the time frame to be cited in the noncompliance declaration.)

2. A statement of the testing to be performed and a copy of the test method.

3. A listing of all equipment to be used in the testing.

4. Documentation that all equipment used in the testing will be properly calibrated.

5. The number of certified systems assembled during the period covered by the noncompliance declaration.

6. A timetable for the correction of all affected systems.

7. Provisions to submit copies of all test data for FDA view.

8. A draft notification letter to affected purchasers or a copy of the letter that was sent.

Assemblers certainly will not submit such detailed information in their initial response to the district. Once a CAP is received, the district should perform a review, and if further guidance is required, contact the Diagnostic Devices Branch (HFZ-322) at (301) 594-4591. Since submission of a CAP represents a commitment to correct the violative products, an establishment inspection should be scheduled to collect the recall information required by the R & R.

During this inspection the investigator may obtain the above commitments regarding the CAP. If an inspection cannot be conducted in a timely manner, a letter to the assembler requesting the required information may be sent in lieu of an establishment inspection.

An establishment inspection at this point may check that all items enumerated above can be provided. The investigator should confirm the following:

- The assembler has the test equipment to perform the required testing.

- Measurement equipment is properly calibrated.

- The adequacy of any test method to be used in compliance testing.

- The assembler has maintained records for tracing assemblies of diagnostic x-ray systems.

- The assembler has adequate personnel to perform the testing.

- The assembler is capable of meeting specified timetables for correction of all systems.

You should consider granting a 30-day grace period for submitting the above information. Assemblers may require this much time to prepare an adequate CAP. If additional time is required, advise the

assembler in writing that he must provide the user notification to affected purchasers within 15 working days of receiving this letter or he will be in violation of The Federal Food, Drug, and Cosmetic Act (the Act), section 538(a)(2) of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of l968).

Please note: Exemptions usually only apply to products already introduced into commerce, not to future or ongoing installations. A variance may be requested and granted for a manufacturer to continue the introduction of products into commerce which do not comply with a part of the Performance Standard in accordance with 21 CFR 1010.4.

(SAMPLE USER NOTIFICATION LETTER FOR DISTRICT ORDERED ASSEMBLER RECALL AND CAPS)

CERTIFIED MAIL RETURN RECEIPT REQUESTED

DOCTOR'S NAME
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (Addressee) :

(Firm name i.e.: ABC X-ray Company) has been advised by the Food and Drug Administration (FDA) that diagnostic x-ray systems assembled by ABC X-ray Company since January 1, 1985, may fail to comply with the Performance Standard for Diagnostic X-ray Systems and Their Major Components (Performance Standard). The FDA advised that (number, i.e.: 43) percent of the (number, i.e.: 27) systems they tested failed to comply with the Performance Standard for Diagnostic X-ray Systems and Their Major Components, Title 21, Code of Federal Regulations, Section 1020.30.

We are working with the FDA to develop a plan for testing all diagnostic x-ray systems we have installed since (date, i.e.: June 1, 1985). Any system we test which fails to comply with the Performance Standard will be adjusted and re-calibrated as necessary to correct the noncompliance. This will be done at no cost to you, the purchaser/ user.

Correction of noncompliant diagnostic x-ray systems is a requirement of the Federal Food, Drug, and Cosmetic Act, section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of l968).

We shall contact you shortly to test your diagnostic x-ray system, and make the necessary adjustments.

Sincerely,

John Doe
ABC X-ray Company

(SAMPLE CAP APPROVAL LETTER TO X-RAY ASSEMBLERS)

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (Addressee) :

On (date) , the FDA sent you a letter advising that between (mo./day/yr.) and (mo./day/yr.) , (number, i.e. 43) percent of your assemblies of certified diagnostic x-ray systems which were tested for compliance with the Performance Standard for Diagnostic X-ray Systems and Their Major Components (Performance Standard) failed to comply. Of the three options outlined in our letter, you elected to submit a corrective action plan (CAP). A partial CAP was submitted in our letter of (mo./day/yr.) .

On (date) , FDA Investigator(s) from this office visited your firm to obtain further information concerning the details of your proposed CAP. On (date) , you submitted additional information which resulted in your CAP submission being complete.

We understand that you intend to conduct your CAP as follows:

1. You will identify all installations of fully certified diagnostic x-ray systems which you assembled between (mo./day/yr.) and (mo./day/yr.) .

2. You will notify all affected purchasers (via certified mail) concerning your CAP.

3. You will retest all assemblies of fully certified diagnostic x-ray systems (which have not previously been tested by FDA) reported in 1. to determine if each system is in full compliance with the Performance Standard.

4. You will correct all items of noncompliance which you encounter during your retests. You will also notify this FDA office of each of the noncompliances you encounter.

5. _____.

6. _____.

We are approving your CAP contingent upon the following:

1. You will submit monthly status reports which include: (1) the number of systems to be corrected, (2) the number of purchaser notification letters sent, (3) the number of letters returned as undeliverable, (4) the number of systems tested, (5) the number of systems which were noncompliant, and (6) the number of noncompliant systems which were corrected, including details of each noncompliance

   Purchaser notification will be made in accordance with all requirements of 21 CFR 1003.21. This office is to be included in the notification process as if it were a purchaser.
2. _____.

You may commence implementation of your CAP upon receipt of this letter.

Please note that the ABC X-ray Company is responsible for the correction of all certified x-ray systems which you have assembled between (mo./day/yr.) and (mo./day/yr.). Should your CAP prove ineffective, we reserve the right to require you to take more stringent measures.

The Food and Drug Administration classifies corrective action plans for diagnostic x-ray products as recalls. We shall shortly notify you of the classification of this recall and the FDA recall number. When making monthly reports or in any future correspondence relating to this CAP, please reference the recall number. Monthly status reports should be sent to:

(Name)
Recall and Emergency Coordinator, HFR-
Food and Drug Administration
(Street address)
(City, State and zip code)

Please be advised that it is FDA policy to report facts surrounding all noncompliances with the Performance Standard in the FDA Enforcement Report. This publication is available to the public.

If you have any questions concerning this matter, please contact (name) at (address), (telephone number).

Sincerely yours,

District Director